IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

ADVANTAGE BEHAVIORAL HEALTH SYSTEMS; ALBANY AREA COMMUNITY SERVICE BOARD d/b/a ASPIRE BEHAVIORAL HEALTH & DEVELOPMENTAL DISABILITY SERVICES; GEORGIA MOUNTAINS COMMUNITY SERVICES d/b/a AVITA COMMUNITY PARTNERS; CLAYTON COMMUNITY MH/SA/DS SERVICE BOARD; COBB COUNTY COMMUNITY SERVICE BOARD; COMMUNITY SERVICE BOARD OF MIDDLE GEORGIA; GATEWAY COMMUNITY SERVICE BOARD; GEORGIA PINES COMMUNITY SERVICE BOARD; HIGHLAND RIVERS COMMUNITY SERVICE BOARD d/b/a HIGHLAND RIVERS HEALTH; LOOKOUT MOUNTAIN COMMUNITY SERVICE BOARD; MIDDLE FLINT AREA COMMUNITY SERVICE BOARD D/B/A MIDDLE FLINT BEHAVIORAL HEALTHCARE; NEW HORIZONS COMMUNITY SERVICE BOARD; PINELAND BEHAVIORAL HEALTH AND DEVELOPMENTAL DISABILITIES CSB; RIVER EDGE BEHAVIORAL HEALTH; COMMUNITY MENTAL HEALTH CENTER OF EAST CENTRAL GEORGIA d/b/a SERENITY BEHAVIORAL HEALTH SYSTEMS; SATILLA COMMUNITY SERVICES d/b/a UNISON BEHAVIORAL HEALTH; and VIEW POINT HEALTH	Civil Action No. _____ JURY TRIAL DEMANDED

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS, INC; ENDO PHARMACEUTICALS INC.,; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., F/K/A PAR PHARMACEUTICAL HOLDINGS, INC.; QUALITEST PHARMACEUTICALS, INC.; ALLERGAN PLC F/K/A ACTAVIS, PLC; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ALLERGAN FINANCE, LLC F/K/A ACTAVIS INC. F/K/A WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ALLERGAN USA, INC.; MALLINCKRODT LLC; SPECGX LLC; MCKESSON CORPORATION; CARDINAL HEALTH INC.; AMERISOURCEBERGEN DRUG CORPORATION; J M SMITH CORPORATION; and JOHN DOE DEFENDANTS 1 through 80,

Defendants.

COMPLAINT

Plaintiffs, Advantage Behavioral Health Systems; Albany Area Community Service Board d/b/a Aspire Behavioral Health & Developmental Disability Services; Georgia Mountains Community Services d/b/a Avita Community Partners; Clayton Community MH/SA/DS Service Board; Cobb County

Community Service Board; Community Service Board of Middle Georgia; Gateway Community Service Board; Georgia Pines Community Service Board; Highland Rivers Community Service Board d/b/a Highland Rivers Health; Lookout Mountain Community Service Board; Middle Flint Area Community Service Board d/b/a Middle Flint Behavioral HealthCare; New Horizons Community Service Board; Pineland Behavioral Health and Developmental Disabilities CSB; River Edge Behavioral Health; Community Mental HealthCenter of East Central Georgia d/b/a Serenity Behavioral Health Systems; Satilla Community Services d/b/a Unison Behavioral Health; and View Point Health (hereinafter collectively referred to as the "Georgia CSBs" or "CSBs"), hereby file this Complaint pursuant to their statutory and common law authority against Defendants Cephalon, Inc.; Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals Inc.; Endo International plc; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Qualitest Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis, PLC; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Allergan USA, Inc.; Mallinckrodt LLC; Mallinckrodt plc; SpecGx LLC; McKesson Corporation;

Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; J M Smith Corporation; and John Doe Defendants 1 through 80 (Defendants are sometimes referred to herein as "Manufacturer Defendants," "Distributor Defendants," or collectively as "Defendants") for Defendants' violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§1961 *et seq.* ("RICO"), creation of a public nuisance, violations of the Georgia Drug Dealer Liability Act, O.C.G.A. §§51-1-46 *et seq.*, and other causes of action related to their past and on-going campaign of unlawfully, dangerously and deceptively marketing and distributing opioids. The Plaintiff CSBs allege as follows:

INTRODUCTION

1. Dangerous opioid drugs produced and/or distributed by the Defendants are killing people across Georgia at alarming rates, and the CSBs are the first line responders at the center of Georgia's opioid epidemic.

2. The CSBs' role as opioid first line responders is even more pronounced as a result of coronavirus, COVID-19, which has upended all facets of American life, including the delivery of health care by the CSBs to those with likely opioid abuse disorder.

3. It is the policy in the State of Georgia that no person shall be denied care and treatment for drug dependency or drug abuse nor shall services be delayed

at a facility of the state or a political subdivision of the state because of the inability to pay for such care and treatment.[1]

4. It is further the policy in the State of Georgia to hold those who create and financially benefit from illegal drug markets responsible to pay civil damages to persons who are injured as a result of such illegal drug use and proliferation.[2] Those persons include "governmental entities, and others who pay for drug treatments."[3]

5. The Defendant Drug Manufacturers have generated billions of dollars in drug sales through their deceptive and illegal marketing of opioids as safe and effective with a low risk for addiction, and the Defendant Drug Distributors have generated billions of dollars in drug distribution costs while failing to prevent the diversion of dangerously excessive opioids in the State of Georgia.

6. As a result of the Defendants' conduct, lives have been forever altered, and the CSBs have suffered excessive expenditures and other significant economic damages arising from their treatment of Georgians with likely opioid abuse disorder.

[1] O.C.G.A. § 37-7-120.
[2] O.C.G.A. § 51-1-46.
[3] O.C.G.A. § 51-1-46(b).

7. As further alleged below, the CSBs submit claims for the services they provide to Georgians with likely opioid abuse disorder to government payors such as the Georgia Department of Behavioral Health and Developmental Disabilities ("DBHDD") and Medicaid, and to private insurance companies just like other healthcare providers. The CSBs also obtain funding from the counties they serve. Yet, the damages sought by the CSBs are unique to the CSBs themselves. They are not pass-through entities. The CSBs seek the damages they have specifically incurred as a result of Defendants' conduct.

8. One Plaintiff CSB alone has calculated that its past costs related to treating clients with opioid abuse or likely opioid abuse disorder have exceeded the reimbursement it received from its funding sources by more than $17.3 million dollars. The Plaintiff CSBs also project losses due to patients with opioid abuse disorder or likely opioid abuse disorder missing their appointments as costing the CSBs a combined $100 million in the past and in the years ahead.

9. In fact, the Plaintiff CSBs have calculated the costs of treating clients with opioid abuse or likely opioid abuse disorder ranging from approximately $700 - $1,700 per year.

10. In total, the Plaintiff CSBs have spent over $155 million treating patients with an opioid abuse or likely opioid abuse disorder in the past, and they

anticipate spending nearly $250 million on these costs in the next fifteen years. Combined with the cost of missed appointments, the total impact of Defendants' illegal conduct on the Plaintiff CSBs is more than $500 million.

11. These costs are only going to continue as the damages caused by Defendants' continue to mount.

12. The CSBs bring this action pursuant to their statutory and common law authority to redress the financial harm caused by Defendants' improper conduct and to recover damages and other relief to compensate the CSBs for the excessive and significant costs they have borne as a result of Defendants' tortious conduct.

13. In communities with ever-climbing opioid addiction and overdose death rates, the CSBs' role in providing a comprehensive system of care for substance abuse and mental health services has never been more critical. The CSBs have borne the costs, both in money and heartache, of Defendants' tortious actions, which proximately caused and continue to cause injury and damage to the CSBs. Accordingly, the CSBs bring this action to recover money and resources the CSBs have spent to combat and otherwise respond to the opioid epidemic throughout the State of Georgia. The CSBs seek all available: (a) damages for any and all of the CSBs' costs associated with Defendants' unlawful conduct as well as

losses sustained for uncompensated or undercompensated care provided to patients with likely opioid abuse disorders; (b) damages for, and abatement of, the public health epidemic which is a nuisance that Defendants have created, and as a result of which, the CSBs have suffered special injuries; (c) other damages sustained by the CSBs as a result of Defendants' conduct; (d) treble damages; (e) disgorgement of Defendants' unjust profits; (f) punitive damages; and (g) any other equitable relief within this Court's powers to redress and halt Defendants' unlawful practices.

14. Specifically, the CSBs seek economic damages from Defendants as reimbursement for the healthcare costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis and to make the CSBs whole from the harm caused by the Defendants. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, rehabilitation, and other mental health or substance abuse services to patients suffering from likely opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from likely opioid disorders or other related addiction or disease

and their families; (4) costs associated with providing care and counseling for children whose parents suffer from likely opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with likely opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to likely opioid abuse disorder.

PARTIES

PLAINTIFFS

15. CSBs are public corporations created by Georgia's General Assembly that provide substance abuse services.

16. The State of Georgia has recognized "its responsibility for its citizens who are mentally ill or developmentally disabled including individuals … who abuse alcohol, narcotics, or other drugs: and its "obligation to such citizens to meet their needs through a coordinated system of community facilities, programs, and services." O.C.G.A. § 37-2-1(a). The State has further recognized the "policy of this state to provide adequate mental health, …, addictive disease, and other disability services to all of its citizens" and "the policy of this state to provide such services through a unified system which encourages cooperation and sharing of resources among all providers of such services, both governmental and private." O.C.G.A. § 37-2-1(b).

17. CSBs are statutorily responsible for providing mental health, developmental disabilities, and addictive disease services to Georgia residents.[4]

18. As the State's safety net provider for these critical services, the CSBs ensure that mental health and addiction prevention, treatment, and recovery support services are available to individuals and families in Georgia, irrespective of their patients' ability to pay.

19. While they are subject to high-level oversight by Georgia's Department of Behavioral Health and Developmental Disabilities (DBHDD), daily operations and personnel matters are managed by the CSBs' boards and supporting staff.

20. Unlike a traditional "public agency," the CSBs obtain their funding through a variety of sources. In addition to state funding, federal funding, and county funding, they also obtain funding from private insurance companies and cash-paying patients based on the healthcare services they provide.

21. The statute creating CSBs specifically authorizes the CSBs to "enroll and contract with [DBHDD], the Department of Human Services, the Department of Public Health, or the Department of Community Health to become a provider of mental health, developmental disabilities, and addictive diseases services or health,

[4] O.C.G.A. § 37-2-6(a).

recovery, housing, or other supportive services." O.C.G.A. § 37-2-6(a). Thus, although considered "public agencies", the CSBs are required to, on their own, become enrolled providers of these programs.

22. Much like other healthcare providers, such as public hospital systems, the CSBs then submit claims to the applicable program or insurance provider for the services they provide.

23. While not permitted to operate for a profit, Georgia law further expressly authorizes the CSBs to "fix fees, rents, rates, and charges that are reasonably expected to produce revenues, which, together with all other funds of the community service board, will be sufficient to administer, operate, and provide" their statutorily-mandated services. O.C.G.A. §37-2-6.1(f).

24. Despite being public bodies, CSBs have "the power to bring an action in [their] own name[s]." O.C.G.A. §37-2-6.3(b).

25. Even more, Georgia law states that the "debts, obligations, and liabilities of a community service board are not debts, obligations, or liabilities of the state or of the counties in which such board operates." O.C.G.A. §37-2-6.3(d). Therefore, the losses suffered by the CSBs as a result of Defendants' conduct are unique to the CSBs and not shared by the state or the counties in which the CSBs operate.

26. Thus, the CSBs have standing to recover damages incurred as a result of Defendants' acts and omissions and have standing to bring all claims pled herein.

27. There are 23 CSBs serving six regions designated by the Georgia Department of Behavioral Health and Developmental Disabilities ("DBHDD").

28. The statutory framework that created and empowers the CSBs also confers broad authority to take the necessary actions to carry out their mission and serve their respective communities.

29. CSBs provide a wide range of services to fulfill the needs of adults and children with complex behavioral and addictive disease disorders, including opioid addiction. CSBs manage local provider networks, develop educational programs, and administer state and federal grants.

30. CSBs also provide inpatient and outpatient services, including Crisis Stabilization Units offering psychiatric stabilization and detoxification services. CSBs operate multiple residential treatment centers for patients requiring intensive care to treat substance abuse disorders. Some CSBs operate specialized recovery facilities to treat pregnant or parenting women with substance abuse disorders, as well as residential and outpatient centers to treat adolescents with substance abuse disorders. CSBs also provide psychiatric evaluation, counseling in individual and

group settings, peer-to-peer support programs, medication management and court services. Patients who complete treatment at a CSB may qualify for transitional housing, vocational training, transportation, and other support services.

31. CSBs provide health services irrespective of financial circumstances under contracts with the DBHDD, the Department of Human Services, the Department of Public Health, and the Department of Community Health and other state and federal agencies. Some services are billed on a sliding fee schedule or reimbursed on a fee-for-service basis by Medicaid, Medicare, or commercial insurance.

32. The CSBs are on the front lines of the state-wide recognized opioid epidemic. The fiscal requirements and extraordinary costs created by the opioid crisis in Georgia continues to make unprecedented, excessive demands on, and stretch the CSBs budgets, resulting in economic losses directly tied to uncompensated and undercompensated care provided to patients with likely opioid abuse disorder.

33. Plaintiff Advantage Behavioral Health Systems is a CSB with a principal address of 250 North Avenue, Athens, Georgia 30601. Advantage Behavioral Health Systems provides addictive disease services, including

addressing and treating opioid addiction and related issues in the following counties:

- Barrow
- Clarke
- Elbert
- Greene
- Jackson
- Madison
- Morgan
- Oconee
- Oglethorpe
- Walton

34. Plaintiff Albany Area Community Service Board d/b/a Aspire Behavioral Health & Developmental Disability Services (hereinafter "Aspire") is a CSB with a principal address of 601 11th Avenue, Albany, Georgia 31701. Aspire provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Baker
- Calhoun
- Dougherty
- Early
- Lee
- Miller
- Terrell
- Worth

35. Plaintiff Georgia Mountains Community Services d/b/a Avita Community Partners (hereinafter "Avita") is a CSB with a principal address of 4331 Thurmond Tanner Parkway, Flowery Branch, Georgia 30542. Avita provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Banks
- Dawson
- Forsyth
- Franklin
- Habersham
- Hall
- Hart
- Lumpkin
- Rabun
- Stephens
- Towns
- Union
- White

36. Plaintiff Clayton Community MH/SA/DS Service Board is a CSB with a principal address of 157 Smith Street, Jonesboro, Georgia 30236. Clayton Community MH/SA/DS Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in Clayton County.

37. Plaintiff Cobb County Community Service Board is a CSB with a principal address of 3830 S. Cobb Drive, Suite 300, Smyrna, Georgia 30080. Cobb County Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in Cobb County.

38. Plaintiff Community Service Board of Middle Georgia is a CSB with a principal address of 2121-A Bellevue Road, Dublin, Georgia 31021. Community Service Board of Middle Georgia provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bleckley
- Burke
- Dodge
- Emanuel
- Glascock
- Jefferson
- Jenkins
- Johnson
- Laurens
- Montgomery
- Pulaski
- Screven
- Telfair
- Treutlen
- Wheeler
- Wilcox

39. Plaintiff Gateway Community Service Board is a CSB with a principal address of 600 Coastal Village Drive, Brunswick, Georgia 31520. Gateway Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bryan
- Camden
- Chatham
- Effingham
- Glynn
- Liberty
- Long
- McIntosh

40. Plaintiff Georgia Pines Community Service Board is a CSB with a principal address of 1102 Smith Avenue, Suite H, Thomasville, Georgia 31792. Georgia Pines Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Colquitt
- Decatur
- Grady
- Mitchell
- Seminole
- Thomas

41. Plaintiff Highland Rivers Community Service Board d/b/a Highland Rivers Health (hereinafter "Highland Rivers") is a CSB with a principal address of 1503 N. Tibbs Road, Dalton, GA, 30720. Highland Rivers provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bartow
- Cherokee
- Fannin
- Floyd
- Gilmer
- Gordon
- Haralson
- Murray
- Paulding
- Pickens
- Polk
- Whitfield

42. Plaintiff Lookout Mountain Community Service Board is a CSB with a principal address of 501 Mize Street, LaFayette, Georgia 30728. Lookout Mountain Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Catoosa
- Chattooga
- Dade

- Walker

43. Plaintiff Middle Flint Area Community Service Board d/b/a Middle Flint Behavioral HealthCare is a CSB with a principal address of 415 N. Jackson Street, P.O. Drawer 1348, Americus, GA 31709. Middle Flint Area Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Crawford
- Crisp
- Dooly
- Houston
- Macon
- Marion
- Peach
- Schley
- Sumter
- Taylor
- Webster

44. Plaintiff New Horizons Community Service Board is a CSB with a principal address of 2100 Comer Avenue, Columbus, Georgia 31904. New Horizons Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Chattahoochee

- Clay
- Harris
- Muscogee
- Quitman
- Randolph
- Stewart
- Talbot

45. Plaintiff Pineland Behavioral Health and Developmental Disabilities CSB (hereinafter "Pineland") is a CSB with a principal address of 5 West Altman Street, Statesboro, Georgia 30458. Pineland provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Appling
- Bulloch
- Candler
- Evans
- Jeff Davis
- Tattnall
- Toombs
- Wayne

46. Plaintiff River Edge Behavioral Health is a CSB with a principal address of 175 Emery Highway, Macon, Georgia 31217. River Edge Behavioral Health provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Baldwin

- Bibb
- Fulton
- Jones
- Monroe
- Putnam
- Twiggs
- Wilkinson

47. Plaintiff Community Mental Health Center of East Central Georgia d/b/a Serenity Behavioral Health Systems (hereinafter "Serenity") is a CSB with a principal address of 3421 Mike Padgett Highway, Augusta, Georgia 30906. Serenity provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Columbia
- Lincoln
- McDuffie
- Richmond
- Taliaferro
- Warren
- Wilkes

48. Plaintiff Satilla Community Services d/b/a Unison Behavioral Health (hereinafter "Unison") is a CSB with a principal address of 1007 Mary Street, Waycross, Georgia 31503. Unison provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Atkinson
- Bacon
- Brantley
- Charlton
- Clinch
- Coffee
- Pierce
- Ware

49. Plaintiff View Point Health is a CSB with a principal address of 175 Gwinnett Drive, Suite 260, Lawrenceville, Georgia 30046. View Point Health provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Gwinnett
- Newton
- Rockdale

50. The CSBs bring this action pursuant to their statutory and common law authority, including the authority granted to them by O.C.G.A. § 37-2-6.3(b).

51. The CSBs have standing to recover damages incurred as a result of Defendants' actions and omissions. The CSBs have standing to bring all claims pled herein.

DEFENDANTS

Manufacturer Defendants

52. At all relevant times, the Manufacturer Defendants have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including the Northern District of Georgia.

Teva and Associated Companies

53. Defendant Cephalon, Inc. is a Delaware corporation with is principal place of business in Frazer, Pennsylvania. Its registered agent is Corporations Creations Network, Inc. located at 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, DE 19810.

54. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

55. Teva Pharmaceuticals USA, Inc. acquired Cephalon in October 2011.

56. Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and their DEA registrant subsidiaries and affiliates (collectively "Cephalon/Teva") are in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These

opioids include, but are not limited to, Actiq and Fentora. Actiq and Fentora are both formulations of fentanyl citrate, a very potent opioid.

57. The Cephalon/Teva Defendants may be served with process through Teva Pharmaceuticals USA, Inc.'s registered agent at the following address: Corporate Creations Network Inc., 2985 Gordy Parkway, 1st Floor, Marietta, GA 30066.

Endo and Associated Companies

58. Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

59. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355, and is a wholly owned subsidiary of Endo Health Solutions, Inc.

60. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York and is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par

Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par Pharmaceuticals") were acquired by Endo International PLC in September 2015 and serve as operating companies of Endo International PLC.

61. Defendant Qualitest Pharmaceuticals, Inc. is an Alabama corporation with its principal office located in Huntsville, Alabama. Qualitest Pharmaceuticals, Inc. was acquired by Endo International PLC in 2010 and merged with Par Pharmaceuticals in 2010.

62. Endo Health Solutions, Inc., Endo Pharmaceuticals Inc., Par Pharmaceuticals, Qualitest Pharmaceuticals, Inc., and their DEA registrant subsidiaries and affiliates (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These include generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products and the branded opioids Opana (oxymorphone hydrochloride); Opana ER (extended release Opana); Percodan (oxycodone and aspirin); Percocet (oxycodone and acetaminophen); and Zydone (hydrocodone and acetaminophen).

63. The Endo Defendants may be served with process through Endo Pharmaceuticals Inc.'s registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Allergan and Associated Companies

64. Defendant Allergan PLC is an Irish public limited company with its principal place of business in Dublin, Ireland and administrative headquarters and all executive offices located in Madison, New Jersey.

65. Defendant Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan PLC f/k/a Actavis plc. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October, 2012. The combined company changed its name to Actavis PLC in October, 2013.

66. Actavis PLC acquired Allergan PLC in March 2015. The combined company changed its name to Allergan PLC in June 2015.

67. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC f/k/a Actavis PLC. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic business to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories Inc. held the Abbreviated New Drug Applications

("ANDA") for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

68. Defendant Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan PLC's 2016 sale of its generics business to Teva.

69. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis LLC is an indirect subsidiary of Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. As part of Allergan PLC's 2016 sale of its generic business to Teva.

70. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan PLC f/k/a Actavis PLC.

71. Allergan PLC f/k/a Actavis PLC, Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Allergan USA, Inc. (collectively, "Allergan") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including Georgia. These opioids include, but are not limited to, the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Allergan also manufactured promethazine with codeine, which, when mixed with citrus flavored soda, is a commonly abused opioid "cocktail," until it stopped manufacture in 2014 due to negative associations of this drug.

72. The Allergan Defendants may be served with process through their registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805. Alternatively, they may be served at the following address of Actavis Pharma, Inc.'s registered agent: Corporate Creations Network, Inc., 2985 Gordy Parkway, 1st Floor, Marietta, GA 30006.

Mallinckrodt and Associated Companies

73. Defendant Mallinckrodt LLC, a wholly owned subsidiary of Mallinckrodt PLC, is a Delaware limited liability company with its principal place of business in St. Louis, Missouri.

74. Defendant SpecGx, LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt PLC.

75. Mallinckrodt LLC, SpecGx LLC, and their DEA registrant subsidiaries and affiliates (collectively, "Mallinckrodt") are or have been in the business of manufacturing, marketing, selling and distributing opioids throughout the United States, including the State of Georgia, including generic formulations of morphine sulfate, extended release, morphine sulfate, fentanyl transdermal, oral transmucosal fentanyl citrate, oxycodone with acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, naltrexone hydrochloride, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, buprenorphine, and naloxone.

76. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

77. The Mallinckrodt Defendants may be served with process through Mallinckrodt LLC's registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Purdue and Associated Companies (Bankruptcy)

77a. Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Co. Inc. (collectively "Purdue") are similarly situated to the named Manufacturer Defendants, being, at all relevant times, in the business of manufacturing, selling, promoting, and/or distributing brand name opioids (*i.e.*, Oxycontin) throughout the U.S. and Georgia. Purdue, however, is not a named defendant here because of the bankruptcy filings of the Purdue entities and Judge Drain's Second Amended Order Pursuant to 11 U.S.C. §105(a) Granting Motion for a Preliminary Injunction, dated November 6, 2019. By omitting Purdue as a named defendant, the Plaintiff CSBs do not waive their rights and claims against Purdue, and, for the record, the Plaintiff CSBs have duly filed their claims as creditors of Purdue in accordance with the established bankruptcy process. Notwithstanding the foregoing, because of Purdue's central role in the opioid story in Georgia, the Plaintiff CSBs include

herein good faith allegations regarding Purdue's conduct in order to inform and explain the conduct of the named defendants who each and all acted similarly to and in concert with Purdue.

Distributor Defendants

78. At all relevant times, Distributor Defendants were engaged in "wholesale distribution" as defined under state and federal law. Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their legal obligations to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders[5], thereby leading to the foreseeable diversion of these dangerous drugs for illegitimate and/or non-medical purposes.

79. Distributor Defendants' failure to meet their obligations is the reason for the substantial volume of prescription opioids plaguing the United States, including in the Northern District of Georgia.

[5] For purposes of this Complaint, this duty to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders, is referred to as "obligations." For purposes of this Complaint, the term "suspicious orders" shall mean any orders of prescription opioids that are required to be investigated and/or reported under Georgia and/or federal law.

McKesson Corporation

80. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

81. At all relevant times, McKesson operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and delivered substantial amounts of opioid drugs to buyers throughout the United States, including Georgia.

82. Moreover, McKesson operates a distribution center located at 2975 Evergreen Drive, Duluth, Georgia.

83. McKesson is the largest pharmaceutical distributor in North America and delivers approximately one-third of all pharmaceuticals used there. According to McKesson's 2017 Annual Report, the company's "pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico."

84. Defendant McKesson Corporation may be served with process through its registered agent at the following address: Corporation Service Company, 40 Technology Parkway South, Suite 300, Norcross, GA 30092.

Cardinal Health, Inc.

85. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its principal place of business in Dublin, Ohio.

86. At all relevant times, Cardinal Health operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and distributed substantial amounts of opioid drugs to buyers in the State of Georgia. Cardinal Health is a global distributor of pharmaceutical drugs and medical products, and is one of the largest distributors of opioids in the United States. In December 2013, Cardinal Health entered a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. In 2016, Cardinal Health generated $121 billion in revenue.

AmerisourceBergen Drug Corporation

87. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

88. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies,

helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."

89. At all relevant times, AmerisourceBergen operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and delivered substantial amounts of opioid drugs to buyers in Georgia. AmerisourceBergen is registered with the Georgia Secretary of State as a Delaware corporation.

90. Defendant AmerisourceBergen may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

J M Smith Corporation

91. J M Smith Corporation is a Delaware corporation with its principal place of business in Spartanburg, South Carolina. Smith Drug Company is a division of J M Smith Corporation responsible for operating J M Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as "Smith Drug" throughout this Complaint.

92. Smith Drug is a wholesale pharmaceutical distributor primarily serving the eastern United States. At all relevant times, Smith Drug operated as a licensed pharmacy wholesaler in Georgia and delivered substantial amounts of

opioid drugs to buyers in Georgia. Smith Drug operates a distribution center in Valdosta, Georgia.

93. Defendant Smith Drug may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

John Doe Defendants 1 Through 80

94. John Doe Defendants 1 through 10, whether singular or plural, are those entities or persons who marketed and promoted the use of prescription opioid drugs through false, scientifically unsupported or misleading representations: (1) in advertising, medical education presentations, speaking engagements, medical literature, publications, websites, and/or statements to physicians and medical students; (2) through funding or employing "Key Opinion Leaders" as described more fully below; and/or (3) through funding or participating in "Front Groups" as described more fully below.

95. John Doe Defendants 11 through 20, whether singular or plural, are those entities or persons that are wholesale distributors of prescription opioid drugs who: (1) failed to implement an effective system to monitor the distribution of opioid drugs; (2) failed to identify and report suspicious orders of opioid drugs destined to pharmacies and individuals in Georgia to the DEA or Georgia Drugs

and Narcotics Agency; (3) failed to maintain effective controls against diversion of opioid drugs for other than legitimate uses in violation of the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances; and/or (4) otherwise failed to comply with the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances.

96. John Doe Defendants 21 through 30 whether singular or plural, are those officers, directors, executives, or agents who were directly and personally involved in developing and executing the marketing efforts of Manufacturer Defendants or of John Doe Defendants 1-10.

97. John Doe Defendants 31 through 40, whether singular or plural, are those entities or persons who had a responsibility to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of controlled substance prescriptions and who failed in their duty to do so.

98. John Doe Defendants 41 through 50, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the "Opioid Promotion Enterprise" described in Count I of this Complaint or who, through proceeds derived from the "Opioid Promotion Enterprise," including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

99. John Doe Defendants 51 through 60, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the "Opioid Diversion Enterprise" described in Count I of this Complaint or who, through proceeds derived from the "Opioid Diversion Enterprise," including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

100. John Doe Defendants 61 through 70, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in a RICO Enterprise which caused or contributed to this opioid crisis or who, through proceeds derived from a RICO Enterprise, including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

101. John Doe Defendants 71 through 80, whether singular or plural, are those officers, directors, executives, entities, or agents who, by virtue of their position and the legal duties vested in them, had an obligation to monitor, detect, investigate, refuse, and/or report suspicious orders of prescription opioids.

102. The John Doe Defendants are incorporated where any Defendant is referenced in this civil action.

Defendants' Agents

103. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives who were actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

104. This Court has diversity subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, and there exists complete diversity between the parties, *i.e.*, no defendant is a citizen of Plaintiffs' home state of Georgia.

105. Additionally, 28 U.S.C. § 1331 grants this Court federal question subject matter jurisdiction over Plaintiffs' RICO claims as they arise under the Racketeer Influenced and Corrupt Organizations Act ("RICO").[6] This allows the Court to also exercise supplemental jurisdiction over Plaintiffs' other claims

[6] 18 U.S.C. §§ 1961 *et seq.*

because they form part of the same case or controversy as the federal RICO claims.[7]

106. This Court has personal jurisdiction over Defendants because Georgia law grants jurisdiction over nonresidents who transact business within the state, commit a tortious act or omission within the state, or cause a tortious injury that occurs within the state if they derive a substantial source of revenue from goods consumed within the state or engage in persistent conduct within the state.[8] Defendants, by and through their authorized agents, servants, and employees, regularly transacted business in Georgia; manufactured, supplied, and distributed opioids in Georgia from which they received substantial revenue; and further, through their acts and omissions, tortuously caused injuries in Georgia by engaged in a persistent course of conduct in Georgia which violated Georgia law. Because Defendants purposefully directed their actions toward Georgia, consented to be sued in Georgia by registering an agent for service of process, and submitted to the jurisdiction of Georgia when obtaining a manufacturer or distributor license, they have the requisite minimum contacts with Georgia for this Court to constitutionally assert personal jurisdiction over Defendants.

[7] 28 U.S.C. §1367(a).
[8] O.C.G.A. § 9-10-91.

107. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). The Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.[9]

108. Venue is proper in the Atlanta Division of this District under Northern District of Georgia Local Rule 3.1. Venue is further proper in this District pursuant to 28 U.S.C. §1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.

FACTUAL ALLEGATIONS

I. THE OPIOID CRISIS IN GEORGIA

109. "It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot

[9] *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle Nat. Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

be overstated."[10] As the Director of the Centers for Disease Control and Prevention ("CDC") has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[11]

110. Georgia finds itself in the midst of an unprecedented prescription drug crisis, with hundreds of deaths attributable to opioid prescription drug overdoses every year.[12]

111. The State of Georgia had the eleventh highest number of opioid overdoses in the United States between 1999 and 2014.[13] Opioid-involved overdose deaths have not just increased - but exploded by an astonishing 1,000% - since 1999 when these drugs were first meaningfully introduced to the State of Georgia.[14]

---

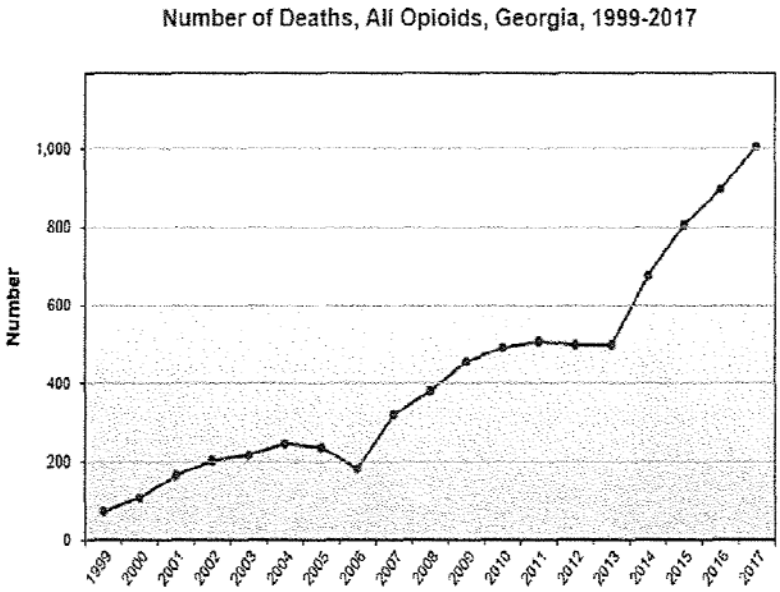
[10] *In re: National Prescription Opiate Lit.*, No. 1:17-MD-02804-DAH, Doc. 1203, at *38 (N.D. Ohio, Dec. 19, 2018).

[11] Thomas R. Frieden & Debra Houry, *Reaching the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 372 NEW ENG. J. MED. 1501, 1503 (2016).

[12] The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015), *available at* https://www.kff.org/other/state-indicator/opioid-overdose-deaths/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited June 12, 2020).

[13] Substance Abuse Research Alliance, *Prescription Opioids and Heroin Epidemic in Georgia*, (2017), *available at* http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf (last visited June 12, 2020).

[14] Online Analytical Statistical Information System ("OASIS"), Drug Overdoses/Opioids Web Query Tool, *available at*



MEASURE	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	1999-2017 TOTAL
Number of Deaths	73	108	164	203	217	246	237	181	321	380	456	491	508	499	499	675	806	897	1,007	7,968

112. Statistics in recent years show the ever-increasing momentum of this crisis: from 2010 to 2016, the total number of documented opioid-involved overdose deaths in Georgia increased by an astounding 117%, from 426 to 929 deaths, and the death rate increased by 111%, from 4.3 to 9.1 deaths/100,000 persons.[15] In 2016, the State of Georgia experienced at least 897 opioid drug-

https://oasis.state.ga.us/oasis/webquery/qryDrugOverdose.aspx (last visited June 12, 2020).

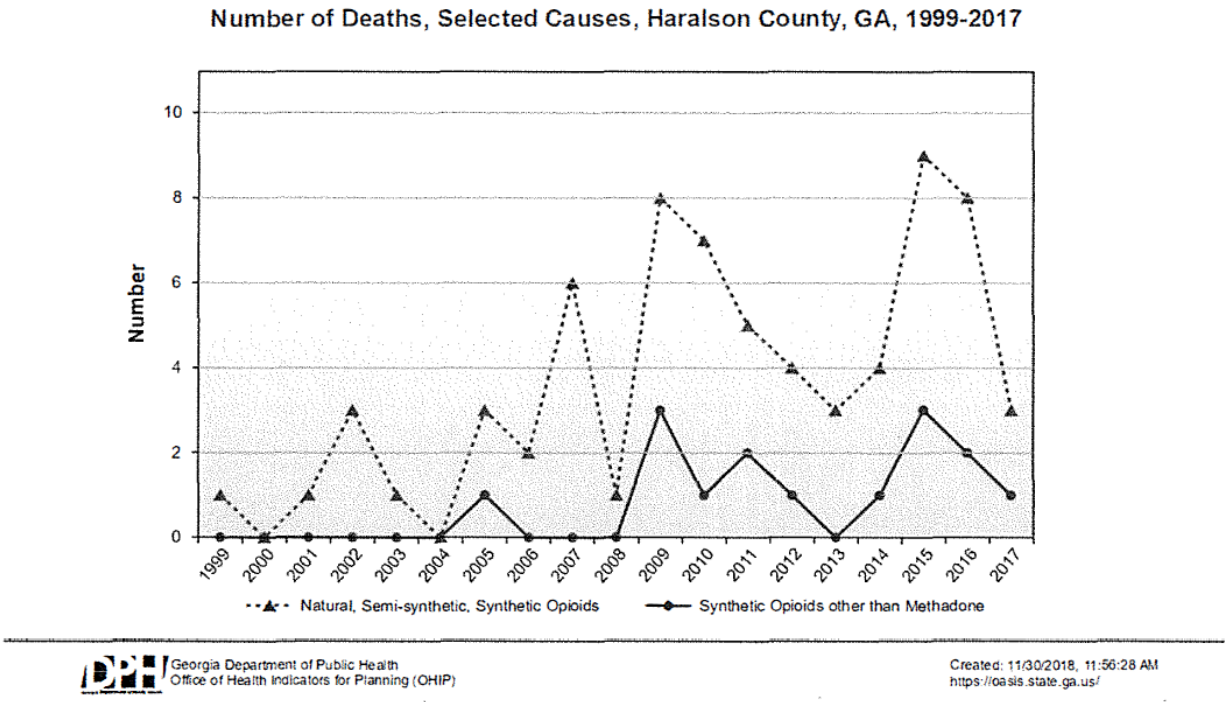
[15] Georgia Department of Public Health, *Opioid Overdose Surveillance, Georgia 2016 (Preliminary Report)* (2016), *available at:* https://dph.georgia.gov/sites/dph.georgia.gov/files/2016%20OPIOID%20PRELIMINARY%20REPORT.FINAL.PDF (last visited June 12, 2020).

related deaths[16] and 9,912 hospital admissions for drug-related disorders. Tellingly, the annual number of such hospital admissions tripled since 2000,[17] with 2,435 documented emergency room visits and 1,709 hospitalizations due to opioid overdoses.[18] In 2017, there were 1,529 deaths attributed to all drugs in the State of Georgia, but an overwhelming number of them (1,007) were the result of opioids.[19] From 1999 to 2017, more people have died from opioid overdoses (7,968) in the State of Georgia than the 2010 total populations of sixteen (16) Georgia counties: Calhoun, Clay, Clinch, Echols, Glascock, Miller, Quitman, Randolph, Schley, Stewart, Talbot, Taliaferro, Treutlen, Warren, Webster, or Wheeler.[20]

113. Haralson County, Georgia, with a population just under 21,000 people[21] has lost almost 70 people to opioid overdoses since 1999.[22]

---

[16] It is anticipated this and other death estimates will increase as this litigation progresses.
[17] Drug Overdoses/Opioids Web Query Tool, *supra* note 10.
[18] *Opioid Overdose Surveillance, Georgia 2016 (Preliminary Report)*, *supra* note 11.
[19] Drug Overdoses/Opioids Web Query Tool, *supra* note 10.
[20] U.S. DEPT. OF COMMERCE, *Georgia: 2010 Population and Housing Unit Counts* (Aug. 2012) at 8, *available at* https://www2.census.gov/library/publications/decennial/2010/cph-2/cph-2-12.pdf (last visited June 12, 2020).
[21] *Id.*
[22] Drug Overdoses/Opioids Web Query Tool, *supra* note 10.



114. Emergency medical services administered the potentially life-saving opioid overdose reversal drug naloxone nearly 10,000 times in 2016 compared to 4,500 times in 2012.[23]

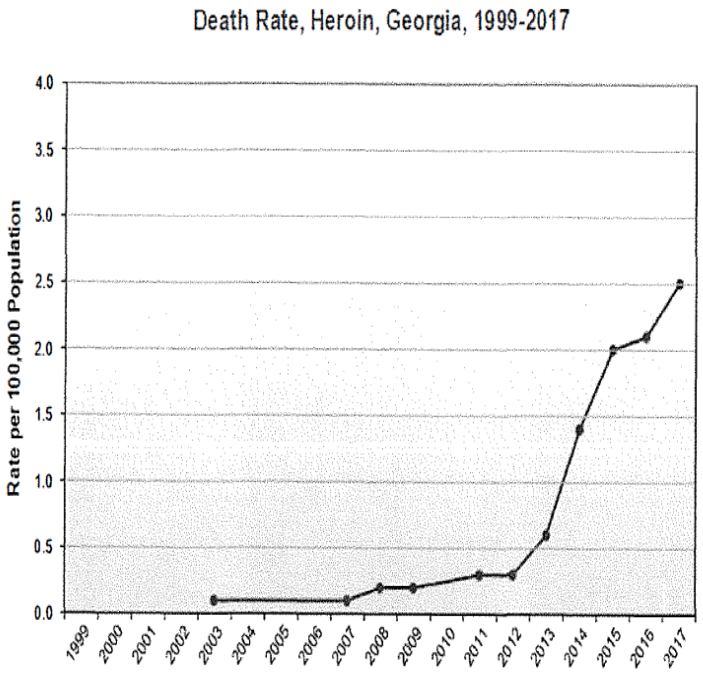
115. The health care costs associated with opioid misuse in Georgia were estimated at $447 million in 2007.[24] Given the explosion in opioid-related deaths,

[23] GEORGIA DEPARTMENT OF AUDITS AND ACCOUNTS PERFORMANCE AUDIT DIVISION, Performance Audit Report No. 17-11, *Opioid Use Disorder—Access to Medication-Assisted Treatment* (Nov. 2017), *available at* www.open.georgia.gov/openga/report/downloadFile?rid=20499 (last visited June 12, 2020).

[24] *Prescription Opioids and Heroin Epidemic in Georgia*, *supra* note 9 at 7.

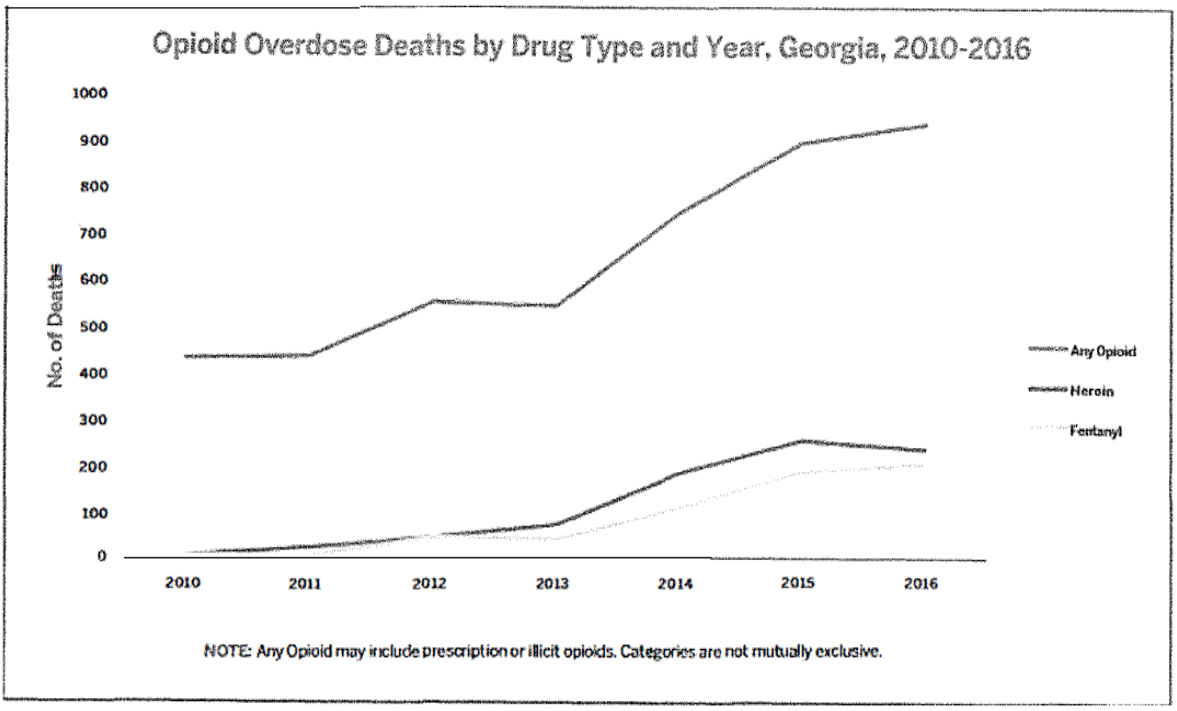
overdoses, and hospitalizations, some estimates indicate that health care costs associated with opioid misuse in Georgia have increased by at least 80%.[25]

116. Heroin overdose deaths have skyrocketed too, as those addicted to prescription opioids often switch to a cheaper alternative to meet their addiction demands. Consequently, the heroin and fentanyl death rates correspond with the increase in opioid-related deaths.



MEASURE	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	1999-2017 TOTAL
Death Rate	*	*	*	*	0.1	*	*	*	0.1	0.2	0.2	*	0.3	0.3	0.6	1.4	2.0	2.1	2.5	0.6

[25] *Id.*

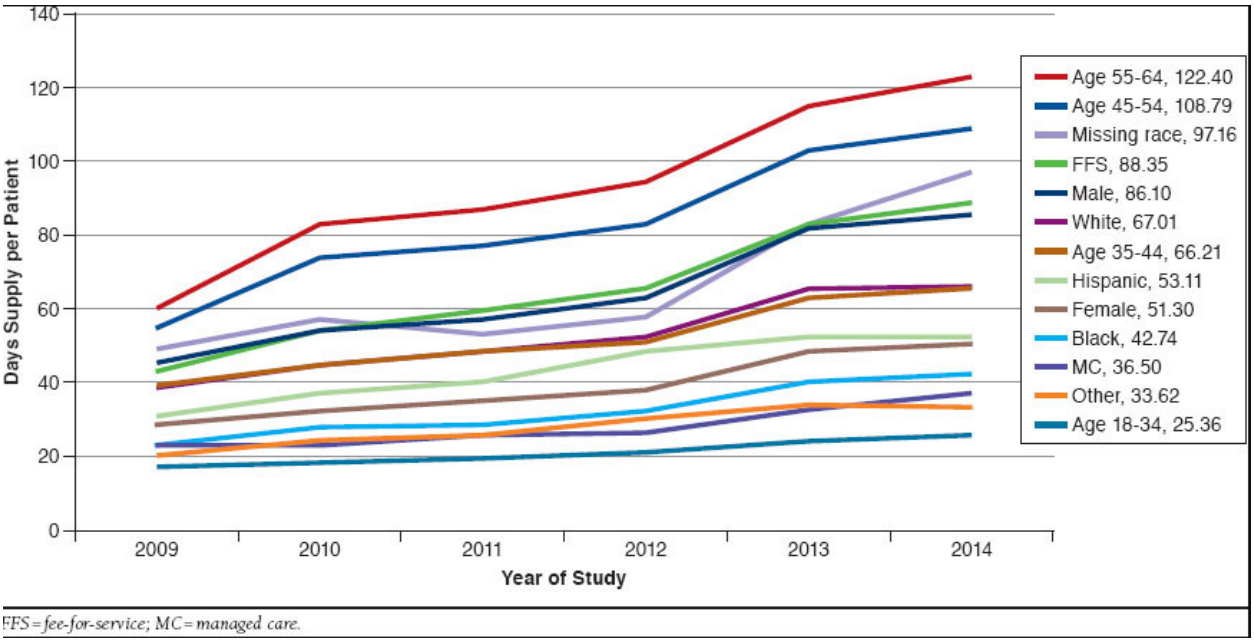


117. The death, addiction, and increased cost associated with prescription opioids is a direct consequence of Defendants' induced Georgia's opioid prescription rate increase over the same time period. By 2013, Georgia's average prescription rate for opioids (86.6% per 100 persons) was well over the national average (79.3).[26] In 2016, there were 0.778 opioid prescriptions per person in Georgia, according to the CDC. Some counties in Georgia had well over 1 prescription per person, including Bacon County (1.57), Catoosa (1.16), Coffee

[26] CDC, *U.S. State Prescribing Rates, Opioids* (2013), https://www.cdc.gov/drugoverdose/maps/rxstate2013.html (last visited June 12, 2020).

(1.73), and Decatur (1.22).[27] According to Georgia Medicaid, the average days' supply of opioids has increased for all age groups from 2009 to 2014:

Average Days Supply of Opioids per Patient by Insurance Type, Age, Gender, Race/Ethnicity, and Year[28]



FFS = fee-for-service; MC = managed care.

118. Not surprisingly, an estimated 180,000 Georgians have an opioid use disorder, which is more than the population of Macon, the fourth largest city in Georgia.[29]

---

[27] CDC, *County Prescribing Rates, Opioids* (2016), https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (last visited June 12, 2020).

[28] Jayani Jayawardhana, Ph.D, Amanda J. Abraham, Ph.D, & Matthew Peri, Ph.D, *Opioid Analgesics in Georgia Medicaid: Trends in Potential Inappropriate Prescribing Practices by Demographic Characteristics*, 2009-2014, 24 JMCP 9 (Sept. 2018), *available at* https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.9.886 (last visited June 12, 2020).

119. As further alleged below, the CSBs have incurred substantial, increasing costs to address and combat this opioid epidemic. Because the opioid epidemic has so deeply and negatively impacted Georgia, the CSBs will continue to incur substantial costs in both combatting and responding to the crisis for years to come.

II. GEORGIA IS PART OF A NATIONAL CRISIS

120. The heartache and financial toll Defendants' have caused to Georgia is part of a larger, national opioid crisis. In 2016, the President of the United States declared that an opioid and heroin epidemic existed within the country.[30] Annual opioid prescriptions now roughly equal the number of adults living in the United States.[31]

121. The opioid crisis is America's deadliest overdose crisis ever. Today, opioids are responsible for the majority of drug overdoses,[32] which have

---

[29] *Opioid Use Disorder—Access to Medication-Assisted Treatment*, *supra* note 19; U.S. CENSUS BUREAU, *Annual Estimates of the Resident Population for Incorporated Places of 50,000 or More, Ranked by July 1, 2017 Population: April 1, 2010 to July I, 2017*, https://www.census.gov/data/tables/time-series/demo/popest/2010s-total-cities-and-towns.html (last visited June 12, 2020).

[30] *See* Proclamation No. 9499, 81 Fed. Reg. 65, 173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[31] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. ENG. J. MED. 1480 (2016).

[32] *Id.*

quadrupled nationally since 1999.[33] In just 2016, CDC data confirms at least 42,249 people died from opioid overdoses, which accounted for the majority (66.4%) of all drug overdose deaths in that year (63,632). From 1999 to 2016, more than 200,000 people have died in the United States from prescription opioid overdoses, and by 2016, people were dying at a rate five times greater than in 1999.[34]

122. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[35] Heroin overdoses have climbed sharply during the opioid epidemic, more than tripling over a four-year period according to the CDC. This increase has been shown to be closely tied to opioid pain reliever misuse and dependence. People who are addicted to prescription opioid painkillers are forty times more likely to

[33] CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Drug Overdose Deaths Data*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited June 12, 2020). Drug deaths take a long time to certify, so this is the most recent available data: U.S. DEPT. OF HEALTH & HUMAN SERVICES, NATIONAL VITAL STATISTICS SYSTEM, *Timeliness of Death Certificate Data for Mortality Surveillance and Provisional Estimates*, Report 001, Dec. 2016, https://www.cdc.gov/nchs/data/vsrr/report001.pdf (last visited June 12, 2020).

[34] CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Prescription Opioid Data*, https://www.cdc.gov/drugoverdose/data/prescribing.html (last visited June 12, 2020).

[35] Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths-United States, 2010-2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1450 (2016).

become addicted to heroin.[36] Heroin is pharmacologically similar to prescription opioids, and most current heroin users report prior non-medical use of prescription opioids before they initiated heroin use. In fact, non-medical use of prescription opioids has been identified to be one of, if not the, strongest serious risk factor for heroin use.[37]

123. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.[38]

124. Additionally, the youngest members of society have been affected by the opioid crisis. According to the CDC, 87 children died of opioid intoxication in 2015, an increase from 16 in 1999. Toddlers and young children are increasingly being found unconscious or dead after consuming an adult's drugs, and there has been a surge of opioid-dependent newborns.

125. Opioids also pose a grave risk to veterans who are twice as likely to die of an opioid overdose than the general population.[39]

---

[36] *See* CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last visited June 12, 2020).

[37] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. ENG. J. MED. 154 (2016).

[38] CDC, CENTERS FOR DISEASE CONTROL & PREVENTION, *Heroin Overdose Data* https://www.cdc.gov/drugoverdose/data/heroin.html (last visited June 12, 2020) (citing Cicero TJ, Ellis MS, Surratt, HL. *The Changing Face of Heroin Use in the United States. A Retrospective Analysis of the Past 50 Years*. JAMA PSYCHIATRY 2014; 71(7):821-826)).

126. Overall, the National Institute on Drug Abuse identifies misuse and addiction to opioids as a "serious national crisis that affects public health as well as social and economic welfare."[40] The economic burden of prescription opioid use alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[41] Since 2001, some estimates have suggested that the opioid crisis has cost the United States more than a trillion dollars, and may exceed over $500 billion over the next three years.[42]

III. THE HISTORY OF OPIOIDS AND ADDICTION

127. Opioids are highly addictive synthetic drugs derived from opium and are otherwise chemically similar to opium alkaloids. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled

---

[39] Wilkie, Robert, Secretary for Veterans Affairs, *Fighting Pain and Addiction for Veterans*, The White House, *available at* https://www.whitehouse.gov/articles/fighting-pain-addiction-veterans/ (last visited June 12, 2020).

[40] NATIONAL INSTITUTE ON DRUG ABUSE, *Opioid Overdose Crisis*, (Rev. Jan. 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited June 12, 2020).

[41] *Id*.; Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose Abuse, and Dependence in the United States, 2013*, MED CARE 2016; 54(10):901-6, *available at* https://www.ncbi.nlm.nih.gov/pubmed/27623005 (last visited June 12, 2020).

[42] Allen, Greg, NPR, *Cost of U.S. Opioid Epidemic Since 2001 is $1 Trillion and Climbing*, https://www.npr.org/sections/health-shots/2018/02/13/585199746/cost-of-u-s-opioid-epidemic-since-2001-is-1-trillion-and-climbing (last visited June 12, 2020).

substances by the DEA since 1970. The labels for scheduled opioids carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" as a result of an excessive dose. The CDC has declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[43]

128. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original and/or faxed copy of a manually signed prescription (which may not be refilled) from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

129. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Manufacturer Defendants, however, have manufactured, promoted, and marketed opioids for the management

[43] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY & MORTALITY WKLY REP 1 (March 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last visited June 12, 2020).

of chronic pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of long-term opioid therapy.

130. Contrary to Manufacturer Defendants' representations, evidence shows that opioid drugs are not effective to treat chronic pain and may worsen a patient's health. One study found that opioids as a class do not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "[O]ther analgesics were significantly more effective than were opioids."[44]

131. In 2013, in response to a petition to restrict the labels of extended-release opioid products, the FDA noted the "grave risks of opioids, the most well-known of which include addiction, overdose, and even death."[45] The FDA further

[44] Andrea D. Furlan, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174 (11) CAN. MED. ASS'N J. 1589-1594 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/ (last visited June 12, 2020). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids.

[45] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, Re: Docket No. FDA-2012-P-088 (Sept. 10, 2013), http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_

warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." The FDA required that, going forward, makers of extended-release opioid formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain - that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[46]

132. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

133. The risks of opioid use disorder and overdose risk are present even when opioids are taken as prescribed.[47] Studies have shown that between 20% and 40% of long-term users of opioids experience problems with opioid use disorders. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose - which itself is a strong predictor of continued opioid use.

Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf (last visited June 12, 2020) [hereinafter Woodcock Sept. 10, 2013 letter].

[46] *Id.* (Emphasis added).

[47] *Id.*

134. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[48]

135. As noted, opioids are extremely addictive. Studies have found diagnosed addiction[49] rates among opioid users in primary care settings as high as 26%.[50] Additionally, among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-abuse disorder.[51]

136. Once a patient begins opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days and surges again when one month of opioids are

[48] Rudd et al., *supra* note 31.

[49] Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 20 I 3) ("DSM-V"). Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

[50] Deborah Dowell et al., *supra* note 39.

[51] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates,* 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria,* 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

prescribed.[52] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[53] In one study, almost 60% of patients who used opioids for 90 days were still using them five years later.[54] When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to – up to and including dosage amounts that are considered by many physicians to be "frighteningly high."[55] And at higher doses, the effects of withdrawal are most substantial, leaving a patient at a much higher risk of addiction.

137. Tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating dosages to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.[56] Patients receiving high

---

[52] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of long-Term Opioid Use - United States, 2006-2015,* 66 MORBIDITY &MORTALITY WKLY REP 265-269 (2017).
[53] *Id.*
[54] Bradley C. Martin et al., *long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study,* 26 J. GEN. INTERNAL. MED. 1450 (2011).
[55] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer loses His Faith,* 170(16) ARCHIVES OF INTERNAL MED. 1422 (20 I 0).
[56] *See* Thomas R. Frieden & Debra Houry, *supra* note 7.

doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.

138. One in every 550 patients on opioid treatment will die within, on average, 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 morphine-milligram-equivalent per day ("MME/day").

139. In short, there are no safe opioid doses, but the higher the dose and the longer the treatment, the more likely a patient will suffer serious health consequences.

140. While the risks and adverse effects of dependence, tolerance, and addiction are disclosed in the labels for Manufacturer Defendants' opioids, they are not disclosed and/or are minimized in Manufacturer Defendants' marketing.

IV. MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

141. The opioid epidemic did not happen by accident.

142. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance

to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

143. In an effort to reverse this common medical understanding, each Manufacturer Defendant conducted, and continues to conduct, a marketing scheme designed to mislead doctors and patients about the safety and efficacy of opioids for the treatment of chronic pain. The result of this scheme has been the use of opioids by a far broader group of patients who are more likely to become addicted and suffer other adverse effects from the long-term use of opioids. Each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

144. Contrary to the language on their drugs' labels, Manufacturer Defendants have made false and misleading claims regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction"; (3) exaggerated the effectiveness of screening tools and management techniques to prevent or mitigate addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) asserted that other methods of pain relief

pose greater risks than opioids; (7) claimed that extended release opioids provided effective pain relief for 12 hours; and/or (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support Manufacturer Defendants' claims.

145. Manufacturer Defendants disseminated these common messages directly, through their sales representatives and in speaker groups led by physicians Manufacturer Defendants recruited for the physicians' support of Manufacturer Defendants' marketing messages, and through unbranded marketing and industry-funded front groups. Through these efforts, Manufacturer Defendants sought to reverse the popular and medical understanding of opioids and their risks.

146. Manufacturer Defendants' efforts have been wildly successful. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to heavy marketing of

opioids to doctors ... [m]any of [whom] were even taught incorrectly that opioids are not addictive when prescribed for legitimate pain."[57]

147. Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating a crisis and causing the harms and damages alleged herein.

A. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids

148. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same message in Georgia as they did nationwide. They spread their false and deceptive statements throughout the State, both by marketing their branded opioids directly to doctors and patients and through seemingly unbiased and independent third parties that they controlled.

149. Manufacturer Defendants' direct marketing of opioids proceeded on numerous tracks. First, each Manufacturer Defendant conducted advertising campaigns touting the purported benefits of their branded drugs, including through advertising in medical journals. Upon information and belief, Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids

[57] Letter from Yivek H. Murthy, M.D., U.S. Surgeon General (Aug. 2016), *available at* http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf (last visited June 12, 2020).

in 2011, nearly triple what they spent in 2001. Many of these branded ads deceptively portrayed the benefits of opioids for chronic pain.

150. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through detailers - sales representatives who visited individual doctors and medical staff in their offices - and small-group speaker programs. Each Manufacturer Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Manufacturer Defendants spent more than $133 million[58] on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. Sales representatives visited hundreds of thousands of doctors and disseminated Manufacturer Defendants' misleading marketing messages. In accordance with common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health Holdings, Inc. (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to precisely track the rates of initial and renewal prescriptions by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

[58] The amount includes $108 million spent by Purdue, $13 million by Teva, $10 million by Endo, and $2 million by Allergan.

151. Third, Manufacturer Defendants marketed their opioids using unbranded advertising, paid speakers and key opinion leaders ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). By funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to promote opioids falsely and misleadingly for the treatment of chronic pain through scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars.

Key Opinion Leaders

152. Two of the most prominent KOLs were Dr. Russell Portenoy and Dr. Lynn Webster. Dr. Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, received research support, consulting fees, and honoraria from Cephalon/Teva, Endo, and Purdue (among others), and was a paid consultant to Cephalon/Teva and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which

endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), which issued education guides for patients, reporters, and policy makers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.

153. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[59] Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."[60]

154. Dr. Lynn Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, a pain clinic in Salt Lake City, Utah. Dr. Webster was

[59] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last visited June 12, 2020).
[60] *Id.*

President of the AAPM in 2013. He is a Senior Editor of Pain Medicine, which published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon/Teva, Endo, and Purdue. At the same time. Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly $2 million from Cephalon/Teva).

155. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to presort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening tools appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo and Purdue.

156. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain* - a book that is still available online - when faced with signs of aberrant behavior,

increasing the dose "in most cases ... should be the clinician's first response."[61] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[62]

Front Groups

157. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to misleadingly promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these Front Groups generated treatment guidelines, unbranded materials, and programs that touted the benefits of and minimized the risk associated with chronic opioid therapy. The Front Groups also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

---

[61] LYNN R. WEBSTER & BETH DOVE, AVOIDING OPIOID ABUSE WHILE MANAGING PAIN (Frederick W. Burgess, M.D. 2007).

[62] John Fauber, *Painkiller Boom Fueled by Networking*, MILWAUKEE WISC. J. SENTINEL, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (last visited June 12, 2020).

158. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content. Manufacturer Defendants also funded their dissemination. In doing so, Manufacturer Defendants made sure that the Front Groups would generate only the messages that Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent entities serving the needs of their members - whether patients suffering from pain or doctors treating those patients.

159. Several of the most prominent of Manufacturer Defendants' Front Groups were the APF, APS, American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[63]

[63] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. On Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), *available at* https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf (last visited June 12, 2020).

160. The most well-known of these was the APF, which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed in May 2012. APF issued education guides for patients, reporters, and policy makers that touted the benefits of opioids for chronic pam and trivialized their risks, particularly the risk of addiction. APF launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes, including death, among returning soldiers. APF also engaged in a significant multimedia campaign, through radio, television and the internet, to educate patients about their "right" to pain treatment, namely opioids. All of APF's programs and materials were available nationally and were intended to reach citizens of Georgia.

161. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to

irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[64]

162. Another Front Group for Manufacturer Defendants was the AAPM. With the assistance, prompting, involvement, and funding of Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

163. The AAPM and the APS issued a joint guideline in 2009 ("AAPM/APS Guidelines") which recommended the use of opioids to treat chronic pain while overstating the benefits and downplaying the risks.[65] Doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, rely upon these treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should

[64] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, WASH. POST, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?noredirect=on&utm_term=.6f519dd9210e (last visited June 12, 2020).

[65] Roger Chou *et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 THE J. OF PAIN 113 (2009), *available at* https://www.jpain.org/article/S1526-5900(08)00831-6/fulltext (last visited June 12, 2020).

cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Allergan, and Purdue discussed the AAPM/APS Guidelines with doctors during individual sales visits.

164. Manufacturer Defendants worked together, through these Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

B. Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids

i. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly understating and misstating the dangerous addiction risks of the opioid drugs.

165. To convince physicians and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations, often aimed at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids, achieved their intended effect. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. The

misrepresentations, described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; (4) opioid dependence can be easily overcome via tapering or other methods; and (5) the use of abuse-deterrent opioids lowers the risk of addiction and overdose. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

166. The first category of false, deceptive, and unfair claims utilized by Manufacturer Defendants to convince doctors that opioids were safe for the long term treatment of pain is that the risk of addiction was low. However these claims are contrary to the longstanding scientific evidence. The CDC explained in its opioid-prescription guideline (the "2016 CDC Guideline") that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose ...)."[66] The

[66] Deborah Dowell et al., *supra* note 39.

2016 CDC Guideline states that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[67]

167. The FDA further exposed the falsity of Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have proved inadequate.[68]

---

[67] *Id*. at 2, 25.

[68] Woodcock Sept. 10, 2013 letter, *supra* note 41; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf (last visited June 12, 2020) [hereinafter Woodcock Mar. 22, 2016 letter].

168. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain and instructed doctors to increase the opioid prescription dose for patients who were already in danger. Dr. David Haddox, who became a vice president at Purdue, termed this supposed henomenon as "pseudoaddiction."

169. The CDC rejected the validity of pseudoaddiction, as it was a reason to push more opioid drugs onto already addicted patients.

170. A third category of false, deceptive, and unfair representations made by Manufacturer Defendants was that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow doctors to reliably identify and safely prescribe opioids to patients predisposed to addiction.

171. The 2016 CDC Guideline confirms the lack of support for these claims. In its guideline, the CDC explains that there are no studies assessing the effectiveness of risk mitigation strategies "or improving outcomes related to overdose, addiction, abuse or misuse."[69]

[69] Deborah Dowell et al., *supra* note 39 at 15.

172. A fourth category of deceptive messaging regarding dangerous opioids is Manufacturer Defendants' misrepresentations that opioid dependence could be easily eliminated. Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use.

173. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion, and premature labor in pregnant women.[70]

174. A fifth category of false, deceptive, and unfair statements made by Manufacturer Defendants to sell more of their drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

[70] *Id. at* 26.

175. Once again, the 2016 CDC Guideline reveals that Manufacturer Defendants' representations were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[71] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[72] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[73] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[74] Additionally, a CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdoses, and that the increased risk rises in a dose-dependent manner. Another study found that higher daily doses and possible opioid misuse were also strong predictors of continued use, and associated with increased risk of overdoses, fractures, dependence, and death.

176. Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example,

[71] *Id.* at 22-23.
[72] *Id.* at 23-24.
[73] *Id.* at 21.
[74] *Id.* at 16.

Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to ... forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[75] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

ii. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly overstating the benefits of the opioid drugs.

177. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there were significant benefits to long-term opioid therapy. Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that scientific evidence supported these benefits.

[75] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc., FDA-2012-P-095 (May 10, 2013), at 5, [hereinafter Woodcock May 10, 2013 letter].

178. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[76]

179. In 2010, the FDA warned Allergan, in response to its advertising of Kadian, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[77] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities ... has not been demonstrated by substantial evidence or substantial clinical experience."

---

[76] Deborah Dowell et al., *supra* note 39 at 15.

[77] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Comm., U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last visited June 12, 2020).

180. Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like nonsteroidal anti-inflammatory drugs ("NSAIDs"), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[78]

181. Purdue and the APF misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours - a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half.

[78] Deborah Dowell et al., *supra* note 39.

182. Cephalon/Teva deceptively marketed and continues to market its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon/Teva from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse which are greatest in non-cancer patients.

iii. Each Manufacturer Defendant Made Materially Deceptive Statements and Concealed Material Facts in the Promotion of Their Opioid Products

Purdue

183. Purdue made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of

chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

184. Illustrative examples of Purdue's false, deceptive and/or unfair claims include the following:

a. Purdue published a pamphlet in 2011 entitled Providing Relief: Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

b. Upon information and belief, Purdue ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

c. Upon information and belief: Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

d. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.[79]

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. Upon information and belief, Purdue sponsored a 2011 webinar, "Managing Patient's Opioid Use: Balancing the Need and Risk,"

[79] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited June 12, 2020).

which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

g. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[80] The guide further taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[81]

j. Purdue (along with Cephalon/Teva) sponsored APF's "Treatment Options: A Guide for People Living with Pain (2007)," which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most

[80] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], *available at* http://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited June 12, 2020).

[81] *Id.* at 32.

appropriate treatment for severe pain.[82] The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."[83] This publication is still available online.[84]

k. Purdue (along with Endo and Cephalon/Teva) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[85] It also taught that relief of pain by opioids, by itself, improved patients' function.[86] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[87]

l. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants, including Purdue, argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[88] The *amicus* brief also argued that "there is no 'ceiling dose"' for opioids.[89]

---

[82] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*] http://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited June 12, 2020).
[83] *Id.*
[84] *Id.*
[85] SCOTT M. FISHMAN, M.D., RESPONSIBLE OPIOID PRESCRIBING: A PHYSICIAN'S GUIDE (2007) at 62.
[86] *Id.*
[87] *Id.*
[88] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.
[89] *Id.*

185. Endo made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations - including over $5 million to the organization responsible for many of the most egregious misrepresentations— that made deceptive

statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

186. Illustrative examples of Endo' s false, deceptive, and/or unfair claims include the following:

a. Endo sponsored a website, "Pain Knowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted" and that opioid

dosages may be increased until "you are on the right dose of medication for your pain." Additionally, upon information and belief, the website claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated National Initiative on Pain Control's ("NIPC") intent to make misleading claims about function.

b. Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

c. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled "Living with Someone with Chronic Pain," which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

d. Endo paid for a 2007 supplement in the Journal of Family entitled "Pain Management Dilemmas in Primary Care: Use of Opioids," which emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

e. Endo distributed and made available on its website (opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, such as construction workers, chefs, and teachers, implying that the drug would provide long-term pain-relief and functional improvement.

f. Endo distributed a pamphlet edited by a KOL entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased ... You won't 'run out' of pain relief."[90]

g. Endo distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[91] It also taught that relief of pain by opioids, by itself: improved patients' function.[92] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[93]

h. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient." Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Endo), argued in an *amicus* brief to the United

[90] Margo McCaffery & Chris Pasero, Endo Pharrn., *Understanding Your Pain: Taking Oral Opioid Analgesics.* (Russell K. Portenoy, M.D., ed., 2004).
[91] Scott M. Fishman, M.D., *supra* note 81 at 62.
[92] I*d.*
[93] *Id.*

States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[94] The *amicus* brief also argued that "there is no 'ceiling dose"' for opioids.[95]

Mallinckrodt

187. Mallinckrodt made and/or disseminated deceptive statements and concealed facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Mallinckrodt exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Mallinckrodt exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Mallinckrodt knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Mallinckrodt exercised final editorial control and approval, which presented an unbalanced

[94] Brief of APF, *supra* note 84 at 9.
[95] *Id.*

treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of

chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

188. Illustrative examples of Mallinckrodt's false, deceptive, and/or unfair claims include the following:

a. Mallinckrodt, through an organization it controls called the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which ostensibly is devoted to responsible prescribing and reducing opioid pain medication abuse, published a book titled *Defeat Chronic Pain Now!* That made the following misrepresentations:

1. “Only rarely does opioid medication cause a true addiction; It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”

2. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

3. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

4. "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

5. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't

have a prior history of 'any addiction and (2) he only takes the medication to treat pain.

6. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction. When prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[96]

c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Mallinckrodt), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[97] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[98]

Cephalon/Teva

189. Cephalon/Teva made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

[96] MALLINCKRODT PHARMACEUTICALS, http://www.mallinckrodt.com/corporate-responsibility/responsible-use (last visited June 12, 2020).
[97] Brief of APF, *supra* note 84 at 9.
[98] *Id.*

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and break through chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon/Teva's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon/Teva' s rapid-onset opioids;

h. Directing its marketing of Cephalon/Teva's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon/Teva's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

190. Illustrative examples of Cephalon/Teva's false, deceptive and/or unfair claims include the following:

a. Cephalon/Teva (along with Purdue) sponsored APF's "Treatment Options: A Guide for People Living with Pain" (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[99] The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."[100] This publication is still available online.[101]

b. Cephalon/Teva (along with Endo and Purdue) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[102] It also taught that relief of pain by opioids, by itself, improved patients' function.[103] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[104]

---

[99] APF, *Treatment Options*, *supra* note 78, at 12.
[100] *Id.*
[101] *Id.*
[102] Scott M. Fishman, M.D., *supra* note 81 at 62.
[103] *Id.*
[104] *Id.*

c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Cephalon/Teva), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[105] The *amicus* brief also argued that "there is no 'ceiling dose"' for opioids.[106]

Allergan

191. Allergan made and/or disseminated deceptive statements and concealed materials facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

192. Illustrative examples of Allergan's false, deceptive and/or unfair claims include the following:

[105] Brief of APF, *supra* note 84 at 9.
[106] *Id*.

a. Allergan's predecessor caused a patient education brochure, "Managing Chronic Back Pain," to be distributed beginning in 2003 that admitted that opioid addiction is possible, but misleadingly claimed that it is "less likely if you have never had an addiction problem." Based on Allergan's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Allergan continued to use this brochure in 2009 and beyond.

b. Upon information and belief Allergan distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Allegran), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[107] The *amicus* brief also argued that "there is no 'ceiling dose"' for opioids.[108]

iv. Manufacturer Defendants Have a History of Criminal and Civil Charges for their Unlawful Conduct.

193. In 2007, Purdue settled criminal and civil charges concerning its misbranding of OxyContin and entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly $635 million in fines, and three of

[107] Brief of APF, *supra* note 84 at 9.
[108] *Id*.

its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.[109]

194. In 2008, Cephalon/Teva pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.[110]

195. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in southeastern Indiana was linked to injection of the prescription painkiller Opana,[111] the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The

[109] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html (last visited June 12, 2020).
[110] U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last visited June 12, 2020).
[111] State of Indiana Health Department, *HIV Outbreak in Southeastern Indiana* (Feb. 25, 2015), *available at* https://calendar.in.gov/site/isdh/event/hiv-outbreak-in-southeastern-indiana/ (last visited June 12, 2020).

agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[112]

196. In 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[113] Mallinckrodt was aware that it was fulfilling suspicious orders through chargeback data it collected to provide rebates or other discounts to the distributor or other third parties. Manufacturers of pharmaceuticals offer discounts, known as "chargebacks," based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The settlement requires a manufacturer to utilize chargeback and similar data to monitor and report to the DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.

---

[112] CNN Wire, *FDA wants Opioid at Center of Scott County HIV Outbreak Pulled Off Market*, FOX59.COM (June 9, 2017) https://fox59.com/2017/06/09/fda-wants-opioid-at-center-of-scott-county-hiv-outbreak-pulled-off-market/ (last visited June 12, 2020); FDA, *FDA Requests Removal of Opana ER for Risks Related to Abuse*, (June 8, 2017) https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm (last visited June 12, 2020).

[113] U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (last visited June 12, 2020).

V. DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

197. While Manufacturer Defendants created the demand for opioids, Distributor Defendants accelerated the opioid crisis which is arguably the worst drug crisis in Georgia and American history. Distributor Defendants serve as the critical choke point. They are obligated in Georgia, as well as to all states they do business in, to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of prescription opioids destined for dispensing physicians and pharmacies in Georgia. If they fail in their duty, the foreseeable harm to the State of Georgia is the diversion of prescription opioids for illegitimate purposes.

198. Faced with this critically important duty, Distributor Defendants ignored it, and over time, flooded the market with opioid prescription drugs. These actions led to the widespread diversion of opioids for illegitimate purposes, which foreseeably devastated the communities the CSBs serve.

199. Distributor Defendants' unlawful conduct was actively concealed from the government authorities for years. One of the ways wholesale distributors are supposed to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders Systems (ARCOS) database. This database contains monthly reports from

each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis. The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. This data, when viewed in its total form will illustrate Distributor Defendants' indifference to their obligations. Additional discovery will reveal the full extent of Distributor Defendants' conduct.

A. Wholesale Drug Distributors are Obligated under Federal and State Law to Monitor, Detect, Report, Investigate, or Otherwise Prevent the Fulfillment of Suspicious Orders.

200. Opioids are a controlled substance and are categorized as having a "high potential for abuse" under Georgia law. *See* O.C.G.A. § 16-13-24; *see also* 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

201. Distributor Defendants have numerous obligations under Georgia law related to the distribution of controlled substances. These obligations include the requirement that they operate in compliance with applicable Federal, State and local laws and regulations, including, among other things, the Georgia Controlled

Substances Act, O.C.G.A. § 16-13-1, *et seq.* ("GCSA"), and the federal Controlled Substances Act.[114]

202. Each Defendant is required, pursuant to the GCSA, to register with the Georgia State Board of Pharmacy. Registration as a distributor in Georgia is contingent upon Distributor Defendants' maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. *See, e.g.*, O.C.G.A. § 16-13-36. The State of Georgia relies on each Distributor Defendant's representation that it meets its duties.

203. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substances Act. *See* GA. COMP. R. & REGS. 480-7-.03(10); 21 U.S.C. § 823(b), (e); and 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

[114] *See* GA. COMP. R. & REGS. 480-7-.03(10) ("Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations" and "[w]holesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations").

204. Manufacturers and wholesale distributors have a duty to maintain adequate records of transactions involving a controlled substance. O.C.G.A. § 16-13-39.

205. Distributor Defendants are further obligated to "design and operate a system to disclose to the registrant [distributor] suspicious orders of controlled substances." *See* 21 C.F.R. § 1307.74(b); *see also* GA. COMP. R. & REGS. 480-7-.03(10).[115] Once discovered, Distributor Defendants have a duty to maintain records of suspicious orders of controlled substances received (GA. COMP. R. & REGS. 480-20-.02) and automatically submit reports of any suspicious orders of controlled substances to the Georgia Drugs and Narcotics Agency (O.C.G.A. § 26-4-115).

206. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. O.C.G.A. § 26-4-115; 21 C.F.R. § 1301.74(b).

[115] *See also* HOMA and the National Association of Chain Drug Stores ("NACDS"), 2016 WL 1321983, at *4 ("[R]egulations ... in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).") [hereinafter Brief for HOMA and NACDS].

207. The suspicious order criteria are disjunctive and are not all inclusive.[116] For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. Distributor Defendants know all of this information in the course and scope of their operations.[117]

208. In addition to reporting all suspicious orders, distributors know they must also stop shipment on any order flagged as suspicious, and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the ***distributor*** can determine that the order is not likely to be diverted into illegal

[116] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No.14-8 [hereinafter Rannazzisi Dec. 27, 2007 letter].

[117] *Id.*

channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36487-01, 36501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

209. Fulfilling these obligations plays a critical role in protecting against the diversion of controlled substances. As the DEA advised all registrants, including each Defendant, in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[118] According to the DEA, "***[t]his responsibility is critical***, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and "just one distributor that uses its DEA registration to facilitate diversion ***can cause***

[118] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Sept. 27, 2006 letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in *Cardinal Health, Inc.* v. *Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

enormous harm."[119] Thus, all Defendants knew how critical their responsibility was to society, including to the State of Georgia.

210. In a second letter to all DEA registrants on December 27, 2007, the DEA again reminded Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[120] The letter further explained:

a. "Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders." Their responsibility "does not end merely with the filing of a suspicious order report ... [they] must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

b. Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious."

c. "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a

[119] *Id.* at 2. (emphasis added).
[120] *See* Rannazzisi Dec. 27, 2007 letter, *supra* note 112.

system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order."

d. A drug distributor must, when reporting a suspicious order, "be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating 'excessive purchases' do not comply with the requirement to report suspicious orders, even if the registrant calls such reports 'suspicious order reports.'"

e. Critically, drug distributors that "routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration."[121]

211. Distributor Defendants knew they were required to monitor, detect, investigate, report, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association ("HDMA"), the trade association of pharmaceutical distributors, explain that distributors are

[121] *Id.*

"[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: if an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[122]

212. Distributor Defendants acknowledge that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but ***undertake such efforts as responsible members of society***."[123] Each Distributor Defendant owes a duty to satisfy its obligations under state and federal law to prevent the diversion into illicit markets in the state.

---

[122] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,* filed in *Cardinal Health, Inc. v. Holder*, No.12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

[123] *See* Brief of Healthcare Distribution Management Association as *Amicus Curiae* for Cardinal Health, 2012 WL 1637016, at *2, filed in *Cardinal Health, Inc. v Department of Justice*, No. 12-506 l (D.C. Cir. 2012). (emphasis added).

B. Distributor Defendants Breached their Duties

213. Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids originating from pharmacies and dispensers in Georgia, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia residents.

214. Each Distributor Defendant sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Georgia and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to residents of the state.

215. The sheer volume of prescription opioids distributed to pharmacies in the State of Georgia, and/or to pharmacies and dispensing physicians from which Distributor Defendants knew the opioids were likely to be diverted into the state, is and was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no legitimate distributor of controlled substances can reasonably claim ignorance of them.[124]

216. Distributor Defendants breached their duty to design and operate a system to disclose to the registrant suspicious orders of controlled substances.

---

[124] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316-01, 62322 (2012)).

217. Distributor Defendants failed to meet their reporting obligations related to suspicious orders originating from the state, and/or which Distributor Defendants knew were likely to be diverted to the state, to state and federal authorities, including the Georgia Drugs and Narcotics Agency ("GDNA") and the DEA.

218. Not only did they fail to report, but Distributor Defendants unlawfully filled suspicious orders in the State of Georgia and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia.

219. The foreseeable harm resulting from Distributor Defendants breach of these duties was the diversion of prescription opioids for illegitimate purposes, harm to the public interest, and the resulting crisis plaguing Georgia today.

220. Because of Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. These actions include the following:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, FL distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn,

Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would pay a $13.25 million civil fine and "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;"

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Stafford Facility. The document also referenced allegations by the DEA that Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, GA, Valencia, CA and Denver, CO;

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland

Facility for failure to maintain effective controls against diversion of oxycodone. Violations included exponentially increasing shipments of Oxycodone to several known pill mills in Florida subsequent to the MOA agreed upon to resolve the prior ISO in 2008 at the Lakeland Facility (shipments of Schedule II opioids to these four pharmacies increased 803% from 2008 to 2009, and 162% from 2009 to 2010);

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility, for failing to report suspicious orders of controlled substances; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI, Lakeland, FL, Landover, MD, La Vista, NE, Livonia, Ml, Methuen, MA, Santa Fe Springs, CA, Washington Courthouse, OH and West Sacramento, CA.

221. The unlawful conduct by Distributor Defendants is purposeful and intentional and Distributor Defendants acted with actual malice in breaching their duties. Distributor Defendants refused, and continue to refuse, to abide by the duties imposed by state and federal law which are required to legally acquire and maintain a license to distribute prescription opiates. These repeated failures over an extended period demonstrate wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others, and Georgia CSBs in particular.

C. Distributor Defendants Used the Courts and the Legislative Process in an Effort to Exculpate their Wrongs and Misrepresented their Compliance with their Legal Duties

222. Distributor Defendants have used the courts and the legislative process in an effort to exculpate their wrongful conduct, and to further avoid their obligations to report and halt fulfillment of suspicious orders. Additionally, Distributor Defendants have repeatedly misrepresented their compliance with their legal duties and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding Distributor Defendants' compliance with their obligations.

223. In *Masters Pharmaceuticals*, the HDMA (a trade association controlled by Distributor Defendants), and the National Association for Chain Drug Stores ("NACDS") submitted *amicus* briefs stating that the legal duty of wholesale distributors was limited to reporting suspicious orders.[125] The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors

[125] Brief for HDMA and NACDS, *supra* note 111, 2016 WL 1321983, at *4-5.

must "decline to ship the order, or conduct some 'due diligence' and- if they are able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. A distributor's investigation must dispel all the red flags giving rise to the suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

224. Additionally, Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[126]

[126] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST, (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.81b689e74928 (last visited

225. In addition to taking actions to limit regulatory prosecutions and suspensions, Distributor Defendants undertook to fraudulently convince government regulators in states like Georgia, as well as the public, that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, Distributor Defendants attempted to assure the public that they were working to curb the opioid epidemic when they were not.

226. For example, a Cardinal Health executive claimed that Cardinal Health uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[127]

June 12, 2020); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST, (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.de8b9282aa72 (last visited June 12, 2020); Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL, (Feb. 18, 2017) https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html (last visited June 12, 2020).

[127] Lenny Bernstein *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASH. POST, (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?noredirect=on&utm_term=.598e585aaf32 (last visited June 12, 2020).

227. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[128]

228. Given Cardinal Health's and McKesson's historical conduct, either these statements are false or misleading, or these companies ignored their monitoring programs.

229. By misleading government regulators and the public about the effectiveness of their controlled substance monitoring programs, Distributor Defendants successfully concealed facts which would have aroused suspicion of the claims that the CSBs now assert while at the same time allowing these Defendants to make billions in profits from this scheme at the expense of the CSBs. The State of Georgia and the CSBs did not know of the existence or scope of Distributor Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Distributor

[128] Scott Higham *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, WASH. POST, (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.b27455c29141 (last visited June 12, 2020).

Defendants, however, knew that government regulators and the public would rely on their statements.

230. The wrongful actions and omissions of Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the CSBs' racketeering allegations below.

231. Distributor Defendants have ignored federal mandates and resisted, defied, and breached their duties under federal and state law, taken advantage of their superior knowledge and position over government entities, and abused the privilege of distributing controlled substances in the State of Georgia, causing enormous harm to the CSBs.

VI. MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

232. Manufacturer Defendants had the same obligations to prevent diversion related to the fulfillment of suspicious prescription opioid orders as Distributor Defendants.

233. Under Georgia and federal law, Manufacturer Defendants are required to comply with substantially the same licensing and permitting requirements as

Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

234. Manufacturer Defendants had access to and possession of the information necessary to meet their legal obligations to prevent diversion of prescription opioids. For example, Manufacturer Defendants engaged in the practice of paying "chargebacks' to opioid distributors and built receipt of this information into the payment structure for opioids. Thus, Manufacturer Defendants knew just as Distributor Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled.

235. Yet, the Manufacturer Defendants have failed to report suspicious orders of controlled substances, specifically including opioids, and violated recordkeeping mandates. For example, the Department of Justice has recently fined Mallinckrodt $35 million for failing to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[129] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator,

[129] U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,* https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (last visited June 12, 2020).

Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."

236. The same duties imposed by federal law on Mallinckrodt were imposed upon all Manufacturer Defendants. Indeed, the Report and Recommendation issued by the federal court overseeing the opioid Multi-District Litigation determined that Manufacturer Defendants, not just distributors, owed a duty to report, investigate, and halt suspicious orders.[130]

237. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

238. Through, *inter alia*, the charge-back data, Manufacturer Defendants could monitor, detect, investigate, report, or otherwise prevent the fulfilment of suspicious orders of opioids yet intentionally and unlawfully failed to do so as required by Georgia and federal law.

---

[130] *In Re: National Prescription Opiate litigation*, No. 1:18-op-45090, 2018 WL 4895856, (N.D. Ohio Oct. 5, 2018) (Report and Recommendation of Magistrate Judge on Defendants' Motion to Dismiss); adopted by the District Court, *In Re: National Prescription Opiate Litigation*, No. 1:18-op-45090, ECF No. 1203, (N.D. Ohio Dec. 19, 2018) (Opinion and Order adopting in part and rejecting in part Magistrate Judge's Report and Recommendation).

239. Manufacturer Defendants have also misrepresented their compliance with Georgia and federal law.

240. Manufacturer Defendants enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

241. The wrongful actions and omissions of Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the CSB's racketeering allegations below.

VIII. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES ARE THE DIRECT AND PROXIMATE CAUSE OF AND/OR ARE A SUBSTANTIAL CONTRIBUTING FACTOR TO THE HARMFUL CONDITIONS, INJURIES, AND DAMAGES ALLEGED HEREIN

242. As Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products. Distributor Defendants' continued indifference to their legal duties led to the unlawful shipment of massive quantities of opioids into Georgia, fueling the epidemic to levels never seen before.

243. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[131]

244. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[132]

245. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[133]

246. The increased abuse of prescription painkillers along with growing sales have contributed to many overdoses and deaths.[134]

247. As shown above, the opioid epidemic has escalated in Georgia with devastating effects on the CSBs and people they serve. Substantial opiate-related substance abuse, hospitalization, and death correlates directly with Defendants' increased distribution of opiates.

---

[131] Dart, Richard, M.D., Severtson G., et al. *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. OF MED. 2015; 372:241-248 (2015).
[132] Elspeth Shipton et al., *Deaths From Opioid Overdosing: Implications of Coroners· Inquest Reports 2008-2012 and Annual Rise in Opioid Prescription Rates: A Population-Based Cohort Study,* PAIN & THERAPY (2012).
[133] *Id.*
[134] *Prescription Opioid Data*, *supra* note 30.

248. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids - like heroin and illicit (i.e., illegally manufactured) fentanyl - the massive distribution of opioids caused the opioid epidemic to become an opioid, heroin, and fentanyl crisis.

249. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for illegitimate purposes into the state.

250. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the state. This diversion and the epidemic are direct causes of foreseeable harms and damages incurred by the CSBs.

251. The CSBs submit claims for the services they provide to Georgians with likely opioid abuse disorder to government payors such as the Georgia Department of Behavioral Health and Developmental Disabilities ("DBHDD") and Medicaid. The CSBs also obtain funding from the counties they serve. Yet, the damages sought by the CSBs are unique to the CSBs themselves. They are not

pass-through entities. The CSBs seek the damages they have specifically incurred as a result of Defendants' conduct.

252. An analysis of the CSBs' claims data specifically related to services provided for likely opioid abuse disorder demonstrates how Defendants' conduct has impaired and continues to impair the CSBs' ability to fulfill their independent front-line healthcare duties and obligations and has caused the CSBs to suffer significant monetary losses.

253. By way of representative example, Gateway Community Service Board (hereinafter "Gateway") services Bryan, Camden, Chatham, Effingham, Glynn, Liberty, Long, and McIntosh counties, an area with an estimated population of 623,000 residents. Gateway provided substance abuse treatment to more than 6,400 unique clients between 2017-2019. The average annual cost of services received by opioid abuse or likely opioid abuse clients was almost $700, which was more than other substance abuse clients.

254. By way of representative example, Lookout Mountain Community Service Board (hereinafter "Lookout Mountain") services Catoosa, Chattooga, Dade, and Walker counties, an area with an estimated population of 178,000 residents. Lookout Mountain provided substance abuse treatment to more than 4,000 unique clients between fiscal years 2012-2015. More than half of the billed

revenue for addiction services provided were for opioid abuse or likely opioid abuse clients. The average opioid abuse or likely opioid abuse clients also required 2 to 3.5 times more services than other substance abuse clients. Additionally, the average annual cost of services received by opioid abuse or likely opioid abuse clients was significantly more than other substance abuse clients. In 2015, the average annual value of services by opioid and likely opioid Lookout Mountain clients was $1,750.53, compared to the average of $502.27 for other substance abuse clients. The average annual cost of services per client was 187% greater for opioid or likely opioid abuse clients than other substance abuse clients.

255. By way of further representative example, Satilla Community Services d/b/a Unison Behavioral Health (hereinafter "Unison") services Atkinson, Bacon, Brantley, Charlton, Clinch, Coffee, Pierce, and Ware counties, an area with an estimated population of 156,000 residents. Unison provided substance abuse treatment to more than 8,400 unique clients between 2012-April 2020. Almost half of Unison clients had an opioid abuse or likely opioid abuse disorder, and the services provided by Unison to these clients accounted for over 60% of Unison's billed revenue. The average annual cost of services per client was over 80% greater for opioid or likely opioid abuse clients than other substance abuse clients.

256. By way of further representative example, View Point Health is a CSB that provides inpatient and outpatient mental health and addictive disease treatment for residents of Gwinnett, Newton, and Rockdale counties (approximately 1,127,000 residents) at more than a dozen locations. Between July 1, 2012 - June 30, 2019, View Point Health provided opioid abuse or likely opioid abuse services to almost 5,000 clients costing more than $57.8 million in care. Additionally, View Point Health clients with an opioid abuse or likely opioid abuse diagnosis:

a. Received 3.7 times more services than other substance abuse clients;

a. Averaged 5.5 more days of detox services than clients with other substance abuse disorders;

b. Were more than 8 times more likely to repeat detox services than patients with other substance abuse disorders;

c. Received services with an average annual cost of more than $1,490, which represents more than an 80% increase compared to other substance abuse clients.

257. View Point Health alone has had to write off more than $17 million in losses for uncompensated or undercompensated care as a result of opioid abuse

services, which are direct losses to this CSB and losses not shared by the counties it serves or the State of Georgia.

258. The Georgia CSBs project their estimated damages for services they have historically provided to patients with likely opioid abuse disorder to be over $150 million, and adding in the almost $40 million in damages related to the cost of missed appointments, the Georgia CSBs project historical damages of nearly $195 million.

259. Further, the Georgia CSBs estimate damages for the services they will have to provide to patients with likely abuse disorder diagnoses in the next fifteen years to be nearly $250 million with more than an additional $60 million related to the cost of missed appointments. The Georgia CSBs estimate total future damages of over $305 million, which combined with the historical damages, is more than $500 million in total damages related to Defendants' conduct.

260. The cost to the CSBs for treating clients with opioid abuse exceeds the reimbursement received from Medicaid, state contracted services through DBHDD, and other insurance payors, both private and public. The CSBs also face additional significant monetary losses for uninsured patients, for patients who do not show up for their appointments, for pharmacy services provided to these patients, and for services provided to family members of their patients who receive

opioid abuse related services. The CSBs have attempted to mitigate their losses from reserves and other funding sources to the great detriment of other programs and much needed capital development projects. Therefore, the opioid crisis has caused direct financial harm to the CSBs.

261. But for Defendants' tortious conduct, including intentional and negligent acts and omissions, the harmful conditions besetting the State of Georgia and the resulting injuries to the Georgia CSBs, as described herein, would not have occurred. Defendants' Defendants' tortious conduct, including intentional and negligent acts and omissions,resulted in direct and foreseeable past, present, and future economic damages for which the CSBs seek relief, as alleged herein. The CSBs also seek the means to abate the epidemic created by Defendants' tortious conduct.

262. The CSBs seek economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering

from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

IX. STATUTES OF LIMITATION ARE TOLLED, AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

A. Continuing Conduct

263. The CSBs continue to suffer harm from Defendants' unlawful actions.

264. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The public nuisance remains unabated.

B. Equitable Estoppel

265. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the CSBs and the communities they serve, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Defendants affirmatively assured the public, that they were working to curb the opioid epidemic.

266. As explained above, Defendants misrepresented the effectiveness of their internal protocol and procedures to prevent diversion as well as their compliance with applicable state and federal laws governing the prevention of diversion.

267. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Distributor Defendants, through their trade associations HOMA and NACDS, filed an *amicus* brief in the *Masters Pharmaceuticals* case, which made the following statements:[135]

[135] Brief for HOMA and NACDS, *supra* note 111, at *3-4, *25.

a. "HOMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

268. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct complied with those obligations.

269. Distributor Defendants have also concealed and prevented discovery of critical information necessary to uncovering their wrongful conduct, including data from the ARCOS database, that would have confirmed their identities and the extent of their wrongful and illegal activities within the state. Moreover,

Defendants used their superior knowledge and position, as well as their ability to operate in darkness, to conceal material facts and to manipulate state entities, including the State of Georgia so they could continue their conduct unabated.

270. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions that the studies did not support. Manufacturer Defendants promoted the concept of "pseudoaddiction" to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, and the State of Georgia, the CSBs, and the public were duped by Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs.

271. Defendants intended that their actions and omissions would be relied upon, including by the State and consumers in the state. Due to Defendants' actions and omissions, the State of Georgia and the CSBs and the residents in the

communities they serve did not know, and did not have the means to know, the truth.

272. The State of Georgia, the CSBs, and the residents in the communities they serve reasonably relied on Defendants' affirmative statements regarding compliance with their legal obligations and consent orders.

C. Fraudulent Conduct

273. The CSBs' claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from, among others, State and Federal regulators and the medical community, including the CSBs. Because of Defendants' active concealment of material information, State and Federal regulators and the medical community, including the CSBs, did not know, or could not have known through the exercise of reasonable diligence, of its causes of action.

274. Defendants' fraudulent misrepresentations, suppressions, and concealments of material facts also constitute a fraudulent concealment from the CSBs of the existence of causes of action by which the CSBs could have sought

recovery from Defendants for its injuries suffered because of Defendants' wrongful conduct.

275. As a proximate result of Defendants' fraudulent misrepresentations, suppressions, and concealments, the CSBs have been, and continue to be, injured and have incurred damages as stated herein.

276. As such, to the extent one would even apply, the limitations period has been tolled, and the CSBs have brought this action upon discovering the existence of the facts underlying the causes of action alleged herein, within the limitations period.

277. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the CSBs filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

278. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased because the public nuisance remains unabated.

279. The medical community, consumers, and the CSBs and the communities they serve were duped by Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state.

280. The CSBs reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

281. The CSBs' claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed from the CSBs. The CSBs did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

282. As a result of Defendants' misrepresentations and deceptive statements about prescription opioids, the CSBs have suffered significant and ongoing damages in multiple ways, including but not limited to (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing

residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

CLAIMS FOR RELIEF

Count I
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO)
(18 U.S.C. § 1961, et. seq.)

(All Defendants)

283. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

284. The goal of Manufacturer and Distributor Defendants was the same: to create a large and excessive market for opioids, to bolster their revenue, to increase their profits, and to grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. Defendants utilized their superior knowledge and posture to accomplish this goal, taking advantage of limited governmental resources to mislead and manipulate

regulators in furtherance of their illegal scheme. Manufacturer Defendants unlawfully marketed their opioids to overturn years of medical concerns regarding the safety and efficacy of opioids for the treatment of chronic pain. And then all Defendants refused to comply with their obligations (and further concealed this refusal) to prevent the diversion of controlled substances so as to continuously expand the quantity of opioids they could manufacture and distribute. As discussed more fully below, Defendants acted in concert through a pattern of racketeering activity to achieve these unlawful goals.

The Enterprises

285. Defendants engaged in a pattern of racketeering activity through the following relevant enterprises in violation of 18 U.S.C. § 1962(c) and, as explained more fully below, in aid of the "Opioid Enterprise":

286. The definition of the term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”[136] This definition encompasses both legitimate and illegitimate enterprises.

[136] 18 U.S.C. § 1961(4).

287. Defendants engaged in two relevant illegal enterprises in violation of these statutes: the Opioid Promotion Enterprise and the Opioid Diversion Enterprise.

288. The Opioid Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Manufacturer Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOL's; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Manufacturing Defendants to fraudulently market opioids as scientifically-proven to be safe and effective. The Opioid Promotion Enterprise functioned as an ongoing organization and continuing unit and was separate and distinct from 1) each of its component entities and 2) from the pattern of racketeering activity carried out by those entities. The Opioid Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity and maintained systematic links through corporate ties, contractual relationships, interrelated financial interests, and continuing coordination of activities for a common purpose: to ensure the prescription of opioids for chronic pain. The Manufacturing Defendants participated in the operation and management of the

opioid marketing fraud enterprise by directing its affairs. Each member of the Opioid Promotion Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers in Plaintiffs' communities.

289. The Opioid Diversion Enterprise is an association-in-fact between Manufacturer Defendants and Distributor Defendants and executed by each of them. In particular, each Defendant was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids and to deceive the public and regulators into believing that Defendants were faithfully fulfilling their statutory obligations.

290. Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiffs suffered injuries caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, Defendants' misconduct

violated Section 1962(c), and Plaintiffs are entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

291. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[137] As discussed in detail below, through Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[138] In doing so, Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

292. Alternatively, Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which Defendants conducted their pattern of racketeering activity in Georgia and throughout the United States. Specifically, the Healthcare Distribution Alliance (HDA) is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit

[137] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).
[138] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, the HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

293. On information and belief, Defendants are members, participants, and/or sponsors of the HDA and utilized it to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern of racketeering activity alleged herein.

294. Each Defendant is a legal entity separate and distinct from the HDA, and the HDA serves the interests of distributors and manufacturers beyond Defendants.

295. The HDA exists separately from the Opioid Diversion Enterprise, and each Defendant exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

296. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the legal enterprise (HDA) were each used by Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the "RICO Enterprise."

297. Each Defendant qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant.134

298. Pursuant to the CSA and the Code of Federal Regulations, Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

299. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

300. At all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription

opioids from which to profit. Defendants conducted their pattern of racketeering activity in Georgia and throughout the United States through this enterprise.

301. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each Defendants; (d) characterized by interpersonal relationships among Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that Defendants would have a larger pool of prescription opioids from which to profit.

302. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold Defendants liable for disregarding their duty to prevent diversion.

303. Members of the Pain Care Forum (PCF) and HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The "Ensuring Patient Access and Effective Drug Enforcement Act" significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

304. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But Defendants' profits were limited by the production quotas set by the DEA, so Defendants refused to identify, investigate, and/or report suspicious orders of their

prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

305. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout Georgia and the corresponding payment and/or receipt of money from the sale of the same.

306. Within the RICO Enterprise, there were interpersonal relationships and common communication by which Defendants shared information on a regular basis.

307. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

308. Each Defendant had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. Defendants participated in

the operation and management of the RICO Enterprise by directing its affairs, as described herein.

309. While Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

310. Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF and HDA, and through their contractual relationships.

311. The PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

312. The Center for Public Integrity and the Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse." Specifically, PCF participants spent over $740 million lobbying in the nation's

capital and in all 50 statehouses on an array of issues, including opioid-related measures.

313. Not surprisingly, each of Defendant who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in PCF. In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Allergan, and Teva. Each Manufacturer Defendant worked together through the PCF to advance the interests of the enterprise. But Manufacturer Defendants were not alone. Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

314. The 2012 PCF Meeting Schedule indicates that meetings were generally held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis. Local members were encouraged to attend the monthly meetings in person, suggesting interpersonal relationships among the members and their representatives.

315. The 2012 PCF Meeting Schedule demonstrates that each Defendant participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug-makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic,

including the concerted lobbying efforts that the PCF undertook on behalf of its members.

316. The HDA also led to the formation of interpersonal relationships and an organization between Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each Distributor and Manufacturer Defendant is a member.

317. The HDA and each Distributor Defendant sought the active membership and participation of Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

318. The HDA touted the benefits of membership to Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."

319. Distributor Defendants and the HDA used membership in that organization as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

320. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants. The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

321. After becoming members, Distributor and Manufacturer Defendants were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems,

operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined

> through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.

322. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the RICO Enterprise's organization.

323. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and Distributor Defendants advertise these conferences to Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry." HDA conferences and the organization as a whole functioned as significant opportunities for Manufacturer and Distributor Defendants to interact at a high-level of leadership. And it is clear that Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

324. Defendants also maintained their interpersonal relationships by working together and exchanging information with the purpose of driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs. Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to Distributor Defendants for sales of prescription opioids.[139] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.[140]

325. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, Distributor Defendants provided Manufacturer Defendants with detailed information regarding

[139] Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, WASH. POST, (April 2, 2017), https://www.pharmacist.com/article/governments-struggle-hold-opioid-manufacturers-accountable (last visited Jan. 10, 2020); *see also* Letter from Sen. Claire McCaskill, (July 26, 2017), https://www.hsgac.senate.gov/imo/media/doc/2017-07-26%20CMC%20requests%20to%20Mallinckrodt,%20Teva,%20Endo,%20and%20Allergan.pdf (last visited Jan. 10, 2020); https://www.hsgac.senate.gov/imo/media/doc/2017-07-26%20CMC%20requests%20to%20McKesson,%20Cardinal%20Health,%20and%20AmerisourceBergen.pdf (last visited Jan. 10, 2020).

[140] *Id.*

their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices.[141] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct Distributor Defendants on how to most effectively sell the prescription opioids.

326. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturer Defendants likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by Defendants as a tool to violate their reporting and anti-diversion duties.

327. Taken together, the interaction and length of the relationships between and among Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage

[141] Webinars, Healthcare Distribution Alliance, (webinar held April 27, 2011), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi (last visited Jan. 10, 2020).

in the unlawful sale of prescription opioids. The HDA and PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of all Defendants were in communication and cooperation.

328. As stated above, the PCF has been lobbying on behalf of Manufacturer and Distributor Defendants for more than a decade, who, from 2006 to 2016, collectively funneled over $740 million through the organization into lobbying efforts across the country on various issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.

329. As described above, Defendants began working together as early as 2006 through the PCF and HDA to promote the common purpose of their enterprise.

330. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

Defendants' Conduct

331. The members of the Opioid Promotion Enterprise worked together to further the enterprise, by and among the following manner and means:

a. Jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;

b. Concealing the addictive qualities of the opioids from prescribers and the public;

c. Misleading the public about the addictive quality and safety and efficacy of opioids;

d. Otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

e. Illegally marketing, selling and/or distributing opioids; and

f. Collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective.

332. To achieve their common goals, Manufacturing Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein, and they actively published misleading information to change the minds of those who already thought opioids to be dangerous. The Manufacturing Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids. They did all of this knowingly and intentionally and accomplished it by working together through relationships formed as part of a common enterprise.

333. During the time period alleged in this Complaint, Defendants exerted control over, conducted, and/or participated in the RICO Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

334. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

335. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

336. Defendants paid nearly $800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass

legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

337. Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

338. Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids. Defendants lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

339. Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

340. Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that Manufacturer Defendants knew included sales that were suspicious and involved

the diversion of opioids that had not been properly investigated or reported by Defendants.

341. Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

342. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings.

343. Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against Distributor Defendants in 178 registrant actions between 2008 and 2012, and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers

include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.

344. Defendants' scheme had a decision-making structure that was driven by Manufacturer Defendants and corroborated by Distributor Defendants. Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

345. Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

346. Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. Defendants influenced the DEA production quotas in the following ways:

a. Distributor Defendants assisted the enterprise and Manufacturer Defendants in their lobbying efforts through the PCF;

b. Distributor Defendants invited the participation, oversight and control of Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. Distributor Defendants provided sales information to Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. Manufacturer Defendants used a chargeback program to ensure delivery of Distributor Defendants' sales information;

e. Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."

f. Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. Manufacturer Defendants used Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of Distributor Defendants by the DEA for failure to report suspicious orders;

j. Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the

"medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA; and

k. The scheme devised and implemented by Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

347. Manufacturer Defendants worked together through Front Groups to intentionally distribute false and misleading information intended to deceive the public about the effects of opioids for the purpose of marketing their dangerous product in service of the Opioid Promotion Enterprise, which in turn served the overall opioid RICO Enterprise by driving up demand for opioids.

Pattern of Racketeering Activity

348. Defendants conducted and participated in the conduct of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. §1961(B), including mail fraud (18 U.S.C. §1341) and wire fraud (18 U.S.C. §1343); and 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

Mail and Wire Fraud

349. Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Plaintiffs, by knowingly conducting or participating in the conduct of the RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

350. Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

351. Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

352. In executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

353. Defendants' predicate acts of racketeering include, but are not limited to:[142]

a. Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

[142] 18 U.S.C. §1961(1).

b. Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

354. Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of Defendants' illegal scheme:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and facilitated Defendants' DEA registrations;

e. Documents and communications that supported and facilitated Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. §827;

g. Documents and communications related to Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the PCF;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

355. Manufacturer Defendants' specific acts of mail and wire fraud in furtherance of the Opioid Promotion Enterprise include but are not limited to,

a. The Federation of State Medical Boards (FSMB)'s publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing," by Fishman;

b. The FSMB's publication of "Revised and Expanded 2nd Edition [of] Responsible Opioid Prescribing[:] A Guide for Michigan Clinicians";

c. The APF's publication of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families";

d. The AAPM's "consensus statement" and educational programs featuring Fine;

e. False or misleading communications to the public and to regulators;

f. Sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

g. Documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

h. Documents to process and receive payment for opioids, including invoices and receipts;

i. Payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

j. Deposits of proceeds; and

k. Other documents and things, including electronic communications.

356. On information and belief, Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

357. Manufacturer Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, the Manufacturer Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to

mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

358. Manufacturer Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with various other affiliates, regional offices, divisions, distributors and other third party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of the Manufacturer Defendants' scheme and common course of conduct to deceive prescribers and consumers and lure consumers into purchasing opioids, which Manufacturer Defendants knew or recklessly disregarded as being unsafe and ineffective for chronic long-term pain and addictive. The Manufacturer Defendants utilized mail and wire transmissions to create an extensive campaign that advertised the exact opposite message: that opioids were safe and effective and rarely if ever addictive.

359. Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

360. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

361. Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

362. Defendants communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

363. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants to annually certify in writing that they had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation

and goals, including false and misleading certifications required annually under the following:

a. Section V of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharm., Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);

b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014); and

c. Section III of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

364. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

365. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities and other criminal activity have been deliberately hidden and cannot be alleged without access to Defendants' books and records. But

Plaintiffs have described the types of, and in some instances, occasions on which numerous predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the items and documents described in the preceding paragraphs.

366. Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for Defendants.

367. Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

Criminal Activity in Relation to Entities and Scheme

368. Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that Defendants were filling on a daily basis—

leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

369. Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

370. Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

371. The predicate acts all had the purpose of generating significant revenue and profits for Defendants while Plaintiffs are left with substantial injuries to their interests through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by Defendants through their participation in the RICO Enterprise and in furtherance of its fraudulent scheme.

372. The pattern of racketeering activity and the RICO Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

373. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

374. Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

375. Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.[143]

[143] 21 U.S.C. § 483(d)(1).

Defendants' Knowledge

376. Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including Manufacturer Defendants' applications for production quotas. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

377. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8K with the SEC announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

378. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the *Los Angeles Times* reported that Purdue was aware of a pill mill operating out of Los

Angeles yet failed to alert the DEA. The *LA Times* uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring." Despite knowledge of the staggering number of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."

379. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.

380. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California and Denver, Colorado;

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

381. These actions against them confirm that Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate

a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that Manufacturer Defendants were aware of the enforcement against their distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

Defendants' RICO Liability

382. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

383. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

384. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on Georgia or Plaintiffs. Defendants were aware that Plaintiffs rely on Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

385. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

386. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

387. Defendants are liable to Plaintiffs under RICO.

RICO Damages

388. Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injuries because Plaintiffs paid for costs associated with the opioid epidemic. These harms are on-going.

389. Plaintiffs' injuries, were, and are being, proximately caused by Defendants' racketeering activities. But for Defendants' conduct, Plaintiffs would not have paid the exorbitant costs and expenditures required as a result of the epidemic, including but not limited to (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related

addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated care related to opioid abuse or likely opioid abuse disorders.

390. Plaintiffs have injuries that were directly caused by Defendants' racketeering activities.

391. Plaintiff seeks all legal and equitable relief as allowed by law, including but not limited to, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre and post-judgment interest.

COUNT II

RICO CONSPIRACY
(18 U.S.C. § 1962(d))

(Against All Defendants)

392. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

393. At all relevant times, Defendants were associated with the RICO Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity. Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.[144]

394. Defendants conspired to violate Section 1962(c), as alleged more fully in Count I, by conducting the affairs of the RICO Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

COUNT III

GEORGIA DRUG DEALER LIABILITY ACT
(O.C.G.A. § 51-1-46, et. seq)

(Against All Defendants)

395. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

396. Georgia's Drug Dealer Liability Act (DDLA),[145] provides a civil remedy against participants in "illegal marketing" of controlled substances for "damages to persons in a community as a result of illegal drug use."[146]

[144] 18 U.S.C. § 1962(d).
[145] O.C.G.A. §51-1-46, et seq.

397. The DDLA defines "participat[ion] in illegal marketing" as "[m]anufacturing, distributing, or delivering or attempting or conspiring to manufacture, distribute, or deliver, a controlled substance" in violation of federal or state law.

398. A controlled substance within the meaning of the DDLA is defined as a substance referenced under O.C.G.A. § 16-13-26(4), which, in turn, is defined as "a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308."[147]

399. Defendants distributed prescription opioids which are included within this list and are therefore controlled substances, including but not limited to, hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, Opana, and Lortab.

400. Defendants did so in violation of state and federal laws such as those which require registered distributors of controlled substances to report suspicious orders.

401. Among the persons to whom the DDLA provides a remedy is "a medical facility, insurer, governmental entity or other legal entity that financially

[146] O.C.G.A. § 51-1-46(d).
[147] O.C.G.A. § 51-1-46(c)(1).

supports a drug treatment or other assistance program for, or that otherwise expends money or provides unreimbursed service on behalf of, the individual abuser."[148]

402. The CSBs pay for drug treatments as contemplated by the DDLA and have expended significant sums of money as a result of the illegal distribution of opioids in Georgia.

403. One of the intents of the DDLA, among others, is "to shift, to the extent possible, the cost of the damage caused by the existence of the illegal drug market in a community to those who illegally profit from that market."[149]

404. The CSBs may bring an action and recover damages under the DDLA on behalf of a person injured by an individual drug abuser for injury resulting from an individual's use of an illegal drug" from "a person who participated in illegal marketing of the controlled substance."[150]

405. The definition of a person injured by an individual drug abuser includes "a medical facility, insurer, governmental entity, or other legal entity that financially supports a drug treatment or other assistance program for, or that

[148] O.C.G.A. § 51-1-46(d)(2)(D).
[149] O.C.G.A. § 51-1-46.
[150] O.C.G.A. § 51-1-46(d)(1).

otherwise expends money or provides unreimbursed service on behalf of, the individual drug abuser."[151]

406. An "individual drug abuser" is one who uses a controlled substance that is not obtained directly from or pursuant to a valid prescription or order of a practitioner who is acting in the course of the practitioner's professional practice or which use is not otherwise authorized by state law.[152]

407. Upon information and belief, individuals acquired and used hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, and/or Opana in the communities the CSBs serve without a valid prescription and/or in a manner not authorized by state law.

408. Those who did so are "individual drug user[s]" under the DDLA.[153]

409. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages.[154]

410. Market share liability obtains if "(A) [t]he defendant was participating in the illegal marketing of the market area controlled substance at the time the individual abuser obtained or used that market area controlled substance; and (B)

[151] O.C.G.A. § 51-1-46(d)(2)(D).
[152] O.C.G.A. § 51-1-46(c)(2).
[153] O.C.G.A. § 51-1-46(c)(2).
[154] O.C.G.A. § 51-1-46(e).

[t]he individual abuser obtained or used the market area controlled substance, or caused the injury, within the defendant's market area."[155]

411. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached the communities and counties the CSBs serve during all times relevant to this complaint. For purposes of the DDLA, Defendants' "market area for the controlled substance" is the entire state of Georgia, because Defendants participated in the illegal drug market by distributing 650 grams or more of a "specified controlled substance."[156]

412. As noted by the Georgia Attorney General's Office, the Georgia market for opioid pills prescribed between June 2016 and May 2017 reached 541 individual doses, or 54 per Georgia Resident. Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least 10 mg of opioid, there can be no question that each Manufacturer Defendant far exceeded the 650 grams level.

413. Manufacturer Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

[155] O.C.G.A. § 51-1-46(e).
[156] O.C.G.A. §§ 51-1-46(c)(1)(6) & (e)(1)(D).

414. As a result, Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids for distribution to Gwinnett County, including "pill mills," and other drug dealers.

415. Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" as well as and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

416. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health and financial resources of the CSBs.

417. Having knowingly participated in the illegal distribution of hydrocodone, oxycodone, oxymorphone, OxyContin, Roxicodone, and/or Opana, the drugs purchased or obtained by residents of Georgia in the "market area of controlled substance," Defendants are liable to Plaintiffs under the DDLA for damages caused by opioids in Georgia including those that were acquired from distribution channels in which Defendants were only market participants.

COUNT IV

PUBLIC NUISANCE

(Against All Defendants)

418. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

419. A nuisance is "anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance."[157]

420. Under Georgia law, a "public nuisance" is defined as one "which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals."[158]

421. "Significant interference with 'the public health, the public safety, the public peace, the public comfort or the public convenience' may support a finding of public nuisance."[159] For example, the illegal dealing of drugs constitutes ample evidence of a public nuisance.[160]

422. The public nuisance caused by Defendants includes the over-saturation, unlawful availability, and abuse of opioids in the state for non-medical

[157] O.C.G.A. § 41-1-1.
[158] O.C.G.A. § 41-1-2.
[159] *City of College Park v. 2600 Camp Creek, LLC*, 293 Ga. App. 207, 208 (2008).
[160] *Moreland v. Cheney*, 267 Ga. 469 (1997).

purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use. Manufacturer Defendants deceptively marketed their opioids to change the prescribing habits of doctors and increase their use for non-cancer chronic pain. Distributor Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called "pill mills" and other dealers.

423. Defendants knew or should have known that their promotion of opioid use and failure to prevent the diversion of opioids for illicit use would create a public nuisance. As a Schedule II controlled substance, prescription opioids are as addictive and dangerous as heroin and, not surprisingly, addiction to prescription opioids has caused an increase in the prevalence of heroin within Georgia.

424. Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so pervasive and widespread and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

425. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by the CSBs, including, but not limited to:

a. The staggering rate of opioid use among adults in Georgia has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths.

b. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created a new secondary market for opioids - providing both the supply of narcotics to sell and the demand of addicts to buy them.

c. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, and financial resources of the CSBs.

d. Adults and children in Georgia who have never taken opioids have also suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids. All of these problems harm the CSBs by diminishing its revenues and forcing it to make increased expenditures on treating opioid abuse related services.

e. The addictive nature of prescription opioids has also spawned a new crisis of heroin and fentanyl abuse and death. Use and overdoses from use of heroin and heroin contaminated with fentanyl have skyrocketed as users have switched from prescription opioids to illegal opioids.

426. The CSBs and the patients they serve have a right to be free from conduct that endangers their health and safety. Yet, Defendants have engaged in conduct which endangers or injures the health and safety of the CSBs and their

patients by their production, promotion, marketing of opioids for use by patients of the CSBs and their failure to monitor, report, and prevent such abuses.

427. The CSBs' resources are being overwhelmed in efforts to address the opioid epidemic.

428. Each Defendant has created or assisted in the creation of a condition that is injurious to the health and safety of the CSBs and their patients, and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods.

429. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of the public peace, order, and safety, fueling the homeless and heroin crises facing the CSBs. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

430. The health and safety of the patients of the CSBs, including those who use, have used, or will use opioids, as well as those affected by the users of opioids, are matters of substantial public interest and of legitimate concern to the CSBs' patients.

431. Defendants' conduct has impacted and continues to impact a substantial number of people within the CSBs' communities and is likely to continue causing significant harm.

432. But for Defendants' actions, opioid use and ultimately its misuse and abuse are widespread, and the massive epidemic of opioid abuse that currently exists could have been avoided.

433. At all relevant times, Defendants possessed the right, ability, knowledge, opportunity, and position to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale in Georgia. Defendants had the power to shut off the supply of illicit opioids into the state, or to control their flow so that widespread diversion did not occur. Defendants could have stopped providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. Had Defendants adhered to their duties, as discussed in detail in this Complaint, there would be no opioid crisis.

434. The opioid crisis created by the Defendants is not a single accident/event or one-off emergency situation necessitating the normal provision of police, fire, and emergency services. Rather, it is a public harm of substantial magnitude that was caused by the Defendants' intentional, repetitive, and persistent course of deceptive conduct.

435. Defendants' intentional misconduct alleged in this case does not concern a discrete event or discrete emergency, and is not part of the normal and

expected costs of a local government's existence. The CSBs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

436. The Defendants designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids

437. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

438. Further, Defendants' conduct has not only impacted the CSBs' delivery of services supported by public funding, but also services supported by cash-paying patients or patients with private insurance.

439. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

440. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

441. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the

CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures, increased medical care services, lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

442. As a direct and proximate result of the public nuisance, the CSBs have sustained harm by spending a substantial amount of money trying to respond, assess, and solve the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off

uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

443. For all of these reasons, this public nuisance is extraordinary in its scope and severity. It is an unprecedented epidemic unseen in Georgia's history. This nuisance is man-made, and a consequence of Defendants' premeditated plan to profit by targeting multiple victims over a prolonged period of time using misconduct, corruption and deceit.

444. The nuisance created by Defendants' conduct is abatable.

445. Defendants should be required to pay the expenses the CSBs have incurred or will incur in the future to respond to this corporate-made crisis and further to fully abate the nuisance.

COUNT V

NEGLIGENCE

(All Defendants)

446. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

447. The elements of negligence under Georgia law are that a defendant has "a legal duty; breached that duty; a causal connection exists between the

defendant's conduct and the plaintiffs injury; and the plaintiff suffered damages."[161]

448. Each Defendant owed a duty of care to CSBs, their patients, and their communities to exercise reasonable care in the manufacturing, marketing, and distribution of highly dangerous opioid drugs in Georgia.

449. In violation of this duty, Defendants have failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in the counties the CSBs serve by misrepresenting the risks and benefits associated with opioids.

450. The injuries and harms to the CSBs and their patients were foreseeable, and in fact were foreseen by each Defendant.

451. Defendants breached this duty by failing to take any action to prevent or reduce the improper and unlawful manufacture, marketing as well as distribution of the opioid drugs.

452. Reasonably prudent wholesale drug manufactures, marketers, and distributors would have anticipated the scourge of opioid addiction that would wreak havoc on communities, including the CBS in the counties they serve, when weighed against Defendants' conduct. Defendants were repeatedly warned by law enforcement. The escalating amounts of addictive drugs flowing through

[161] *Seymour Elec. and Air Conditioning Service, Inc. v. Statom*, 309 Ga. App. 677 (2011).

Defendants' businesses and the sheer volume of these prescription opioids further alerted Defendants that addiction was fueling the increased consumption and that legitimate medical purposes were not being served.

453. Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction.

454. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct. Defendants were negligent in failing to disclose suspicious orders for opioids to the State pursuant to the requirements of Georgia law and the federal Controlled Substances Act.

455. Defendants' acts and omissions combined and concurred to impose an unreasonable risk of harm to others and combined and concurred with the negligent and/or criminal acts of third parties to impose an unreasonable risk of harm to others.

456. Defendants are in a class of a limited number of parties that can legally manufacture and distribute opioids which places them in a position of great trust by the State.

457. The trust placed in Defendants by the State through the license to manufacture and distribute opioids in Georgia creates a duty on behalf of Defendants to prevent diversion of the medications they supply.

458. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their businesses.

459. Defendants are in exclusive control of the management of the opioids they manufacture, market, and distribute in Georgia.

460. The CSBs are without fault and the injuries to the CSBs and the residents they serve would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and distribution of opioids.

461. Defendants' conduct described above created and was the primary cause of the conditions described above - Georgia's opioid crisis, and directly caused Plaintiffs' damages. The cause and conditions giving rise to Plaintiffs' damages resides with Defendants and not prescribing physicians, criminals, or other third parties.

462. Additionally, given the conduct of Defendants and conditions arising therefrom, as described above, the actions of prescribing physicians, criminals, and

other third parties related to excessive opioid use in Georgia was foreseeable, as was the consequence thereof, including excessive prescriptions and criminal drug activity.

463. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

464. Further, Defendants' conduct has not only impacted the CSBs' delivery of services supported by public funding, but also services supported by cash-paying patients or patients with private insurance. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

465. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

466. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures,

increased medical care services, and lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

467. As a direct and proximate cause of Defendants' negligence, the CSBs have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

468. Specifically, the CSBs seek economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and

(6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

COUNT VI

UNJUST ENRICHMENT

(All Defendants)

469. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

470. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

471. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

472. For years, the CSBs conferred a benefit on Defendants by attempting to address all aspects of the opioid epidemic, including, but not limited to: supplying medical care and treatment to opioid users; education, counseling, rehabilitation, and therapy services to opioid users; abatement of nuisances; and other efforts and remedial measures designed to address and curb the increasing epidemic.

473. The CSBs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing, promotion and distribution practices. Moreover, the CSBs have incurred expenditures for treatments and services over and above the CSB's ordinary services.

474. Defendants directly profited from the CSBs' remedial expenditures. Without such expenditures, there would not have been a profitable market for these dangerous and addictive drugs. These expenditures have helped to sustain Defendants' businesses.

475. The opioid crisis created by the Defendants is not a single accident/event or one-off emergency situation necessitating the normal provision of police, fire, and emergency services. Rather, it is a public harm of substantial magnitude that was caused by the Defendants' intentional, repetitive, and persistent course of deceptive conduct.

476. Defendants' intentional misconduct alleged in this case does not concern a discrete event or discrete emergency, and is not part of the normal and expected costs of a local government's existence. The CSBs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

477. The Defendants designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids

478. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

479. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

480. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

481. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures, increased medical care services, and lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

482. Defendants were, and are, aware of these obvious benefits, and their retention of these benefits is unjust. The misconduct alleged in this Complaint is ongoing and persistent.

483. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment that they would not otherwise have obtained. This enrichment was without justification.

484. Defendants have unjustly retained benefits to the detriment of the CSBs, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

485. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of the CSBs.

486. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the CSBs.

487. The CSBs seek an order compelling Defendants to disgorge all unjust enrichment to the CSBs and awarding such other, further, and different relief as this Honorable Court may deem just.

COUNT VII

CIVIL CONSPIRACY

(All Defendants)

488. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

489. Defendants engaged in (1) a common design between two or more persons, (2) to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, (3) an overt act in furtherance of the conspiracy, and (4) resulting in injury to the CSBs.

490. Defendants engaged in one or more unlawful tortious activities to further the conspiracy. The objects of the conspiracy were racketeering, nuisance, negligence, fraud, misrepresentation and other unlawful tortious conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

491. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object of or course of action for this conspiracy. Defendants also knew that their wrongful

actions would inflict injury upon the targets of the conspiracy, including the CSBs and the communities they serve.

492. As described above, Defendants committed multiple unlawful and overt acts to further the object of or course of action for this conspiracy as described above.

493. These unlawful acts proximately caused the damages suffered by the CSBs. Accordingly, the CSBs are entitled to recover their actual damages.

494. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore liable for the damages flowing from the conspiracy.

COUNT VIII

FALSE ADVERTISING
(O.C.G.A. § 10-1-420, et seq.)

(All Defendants)

495. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

496. Defendants, in marketing opioids, made numerous false statements about the nature of these drugs, including:

a. that they are safe;

b. that they are appropriate for the treatment of chronic, non-cancer pain;

c. that they can improve bodily and mental function long-term or otherwise improve quality of life;

d. that they are safe and effective for continued, long-term use;

e. that they are not addictive;

f. that pseudoaddiction is a legitimate medical concept;

g. that patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids;

h. that opioid addiction is the product of problem patients and doctors, not inherently of opioids; and

i. that opioid abuse and addiction manifest themselves through snorting and injecting the drugs, and not oral or topical administration.

497. These false statements were made in order to induce residents of Georgia to purchase Defendants' opioids, and in turn, caused CSBs to expend extraordinary resources and funds to treat such residents.

498. These false statements were disseminated in public in the state through marketing brochures, websites, publications, advertising in periodicals, educational materials, speeches sponsored by Defendants, misleading scientific studies, statements to medical professionals, and endorsement of statements by others.

499. Defendants knew or should have known these statements were false.

COUNT IX

NEGLIGENCE PER SE

(All Defendants)

500. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

501. Georgia law provides that "[w]hen the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby."[162]

502. Defendants were under an obligation to implement a system to monitor, identify, investigate, and halt suspicious orders and to stop and report confirmed suspicious orders. Furthermore, Georgia law incorporates federal requirements set out under the Controlled Substances Act and related controlled substance laws and regulations.

503. Each Defendant has an affirmative duty under Georgia and federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that distributors of Schedule II

[162] O.C.G.A. § 51-1-6.

drugs, including opioids, maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[163] Those requirements are adopted and incorporated into Georgia law, as set out above.

504. Defendants failed to implement an effective system for accomplishing this duty and continued to ship suspicious orders to pharmacies and other dispensers in Georgia, and they did not report such sales to the proper legal authorities of the State of Georgia.

505. As a result, opioid drugs have been diverted, illicitly used, and abused, resulting in thousands of overdoses, hospitalizations, and deaths.

506. That diversion proximately caused the opioid crisis which is the source of the injuries here complained of. Thousands of Georgia residents are now struggling with addiction. Criminal enterprises are increasing the supply of heroin and fentanyl to exploit the market for opioid addiction.

507. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community.

[163] 21 U.S.C. § 823(b)(l); 21 CFR 1301.74; . O.C.G.A. § 26-4-115.

508. The CSBs fall within the class of persons that O.C.G.A. § 26-4-115 and the Controlled Substances Act were intended to protect.

509. The expenses incurred by the CSBs in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 and 21 U.S.C. § 823(b) were intended to prevent or mitigate.

510. The Defendants' illegal activity caused damages to the CSBs including but not limited to costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

511. Defendants are liable for the costs of all of the CSBs' damages including those just listed, other past damages already incurred as a result of

Defendants' actions, and all future damages that will likely occur as a result of those actions.

512. The CSBs seek to recover the cost of all such damages resulting from Defendants' negligence per se.

513. The CSBs seek all legal and equitable relief as allowed by law.

COUNT X

BREACH OF STATUTORY DUTY (O.C.G.A. § 51-1-6)

(All Defendants)

514. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

515. Each Defendant had a duty under federal and state law to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.[164]

516. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community, so drug diversion does not occur.

[164] O.C.G.A. § 26-4-115.

517. These laws are intended to protect the health, safety, and welfare of individuals and communities, such as the CSBs from the deleterious effects of dangerous drugs by prevention their diversion.[165] Thus, they were enacted for the CSBs' benefit.

518. As explained in the facts section of this Complaint, Defendants' failure to monitor and report suspicious orders of opioids and shipment of suspicious orders resulted in injury to the CSBs and the communities they serve.

519. In violation of these laws, Defendants intentionally distributed and/or sold dangerous controlled substances without performing these required duties.

520. Defendants' violations of these laws breached a legal duty to Plaintiff created by the laws.

521. This breach resulted in the type of harm the laws seek to prevent, namely the diversion, illegal sale, and illegal use of dangerous drugs, which caused injury to the CSBs and the communities they serve.

522. Under O.C.G.A. § 51–1–6, Plaintiff is entitled to recover damages for caused by Defendants' breach of their legal duty to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

[165] 21 U.S.C.A. § 801; O.C.G.A. § 26-4-2.

523. The expenses incurred by the CSBs in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 were intended to prevent or mitigate.

524. The CSBs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' tortious activity.

525. The CSBs seek all legal and equitable relief as allowed by law.

PUNITIVE DAMAGES

526. Plaintiffs re-incorporate by reference and re-allege the factual allegations stated in paragraphs 1-287 as though fully set forth herein.

527. The facts set forth above regarding Defendants' conduct, including but not limited to Defendants' fraudulent and intentionally deceptive acts, demonstrate that the Defendants' actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.

528. Defendants' actions had a great probability of causing substantial harm.

529. When such harm materialized, Defendants acted with a prolonged indifference to the dire consequences of their wrongful conduct.

530. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels.

531. Because of the severe level of danger posed by, and indeed visited upon the CSBs the communities they serve, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes.

532. Defendants not only failed to live up this duty, but actively sought to undermine it in order to increase the volume of drugs they could sell.

533. Defendants chose profit over the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrent.

534. In light of Defendants' wrongful conduct, an award of punitive damages is necessary to deter future operations that harm the public.

535. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that gives rise to the presumption of a conscious indifference to consequences.

PRAYER FOR RELIEF

WHEREFORE, the CSBs pray for an Order that this Honorable Court:

A. Enter judgment against Defendants jointly and severally and in favor of the CSBs;

B. Award nominal, economic and/or consequential damages in an amount sufficient to fairly and completely compensate the CSBs for all compensable damages;

C. Award actual and treble damages based on the amount of the CSBs' losses resulting from Defendants' violations of the Racketeer Influenced and Corrupt Organization ("RICO");

D. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;

E. Enter an Order requiring Defendants to fund an "abatement fund" for the purpose of abating the opioid nuisances, and further order Defendants to pay damages sufficient to fund an abatement plan;

F. Award the CSBs the costs of suit, including reasonable attorneys' fees as provided by law;

G. Require Defendants to disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the CSBs; and

H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

The CSBs demand, and are entitled to, a trial by jury on all issues so triable.

Respectfully submitted, this 20th day of August, 2020.

/s/ Charles W. Byrd
Charles W. Byrd
Georgia Bar No. 100850
Jay F. Hirsch
Georgia Bar No. 357185
Michael J. Moore
Georgia Bar No. 520109
Courtney L. Mohammadi
Georgia Bar No. 566460
Elizabeth S. White
Georgia Bar No. 258844

Pope, McGlamry, Kilpatrick, Morrison & Norwood, P.C.
3391 Peachtree Road, NE, Suite 300
P.O. Box 19337 (31126-1337)
Atlanta, GA 30326
(404) 523-7706
efile@pmkm.com
chuckbyrd@pmkm.com
jayhirsch@pmkm.com

michaelmoore@pmkm.com
courtneymohammadi@pmkm.com
lizwhite@pmkm.com

Counsel for Plaintiff CSBs